National DNA Index System (NDIS) Operational Procedures Manual

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NDIS Operational Procedures

Legal Authority

The Federal DNA Identification Act, enacted in 1994, authorized the Director of the Federal Bureau of Investigation (FBI) to establish a national identification index of DNA records. At that time, the FBI was developing software and a program for the storage and exchange of DNA records among forensic DNA laboratories. The Federal DNA Act formalized these FBI efforts and also provided funding for the FBI's Combined DNA Index System (CODIS) program and grants to State and Local forensic DNA laboratories to participate in CODIS. Select provisions of the Federal DNA Act are contained in Appendix A.

The Federal DNA Act specifies the type of DNA records that can be maintained and searched at the national level. No DNA samples are stored at the national level. The Act also describes the requirements for participation in the National DNA Index System (NDIS): a Federal, State or Local criminal justice agency (or the Secretary of Defense); a laboratory accredited by a non-profit professional association of persons actively engaged in forensic science that is nationally recognized within the forensic science community or a criminal justice agency using a Rapid DNA instrument approved by the FBI Director in compliance with standards and procedures issued by the Director; must follow publicly available minimum standards for a quality assurance program for DNA analysis issued by the FBI Director (Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories - QAS); must undergo external audits every two years to demonstrate compliance with these QAS; must limit disclosure of the DNA records and analyses; and must expunge DNA records in the event that a conviction is overturned for a qualifying event/offense or for a qualifying arrest, if there is an acquittal, a dismissal or no charges are filed within the applicable time period. The Federal DNA Act states that "access to the index is subject to cancellation if the quality control and privacy requirements... are not met."

With Congressional authorization for a national DNA index for law enforcement identification purposes, the FBI continued its software development efforts with Federal, State and Local forensic laboratories that were performing DNA analysis. Additionally, in anticipation of the creation of the national DNA database, in 1996, a Privacy Act Notice on a new system of records, NDIS, was published in the Federal Register. As required by law, this Notice contains a description of the individuals covered by the system, the types of DNA records that would be stored and searched in NDIS, the purpose and routine uses of the system, the practices for storing, accessing, and retaining the DNA records as well as records access procedures. The Privacy Act Notice on NDIS is contained in Appendix B.

Operational and/or procedural issues not addressed by the Federal DNA Act, such as the frequency of searches at the national level, are determined by the FBI as administrator of

the National DNA Index System.

DNA Community Involvement

In the early 1990s when the initial version of the CODIS software was being developed, the FBI Laboratory convened a group of privacy advocates to obtain feedback on its plans for this new law enforcement tool. Among the recommendations was the suggestion that, to protect the privacy of persons providing the DNA samples, that no personally identifiable information be databased. This recommendation was incorporated into the CODIS software and the implementation of the National DNA Index and remains in effect today.

As the FBI planned for the implementation of the National Index, processes and procedures were needed on how to seek participation in the National DNA Index, the uploading of DNA records, searching of DNA records at the national level, and the threshold for release of personally identifiable information. As a result, the FBI empaneled an NDIS Procedures Board to develop procedures on the operation of the National DNA Index. Chaired by the Chief of the FBI's CODIS Unit, the current NDIS Procedures Board consists of representatives of the FBI Laboratory's DNA-related units, 6 representatives from State and Local forensic DNA laboratories, the Chair of the Scientific Working Group on DNA Analysis Methods (SWGDAM) and a State CODIS Administrator's representative. The NDIS Procedures Board meets periodically to address issues raised by CODIS users and Administrators; to provide guidance for the users and the FBI on operational issues; and to ensure that such operational procedures are in compliance with Federal law and regulations.

Recommendations from the statutory advisory group, the Federal DNA Advisory Board, have also helped shape the administration of the National DNA Index System.¹ While primarily focused on quality assurance standards, the House of Representatives Judiciary Committee Report on the DNA Identification Act of 1993 demonstrate Congressional intent that the "Board also advise the Director on other scientific and policy questions relating to forensic applications of DNA. In particular, it would be appropriate for the Board to address: (1) the statistical, and population genetics issues that have been raised; and (2) the privacy, law enforcement and technical issues associated with the FBI's program to establish a databank of DNA profiles, known as CODIS."² Pursuant to this legislative direction and its charter, the DNA Advisory Board considered standards for acceptance of DNA profiles in CODIS which take account of relevant privacy, law enforcement and technical issues and concluded that the Federal DNA Act provisions on access and disclosure "sufficiently limit the scope of access to the DNA analyses and

¹ The Federal DNA Advisory Board was established in accordance with 34 U.S.C §12592; this statutory body operated from May 1995 until December 2000.

² House Report 103-45, House of Representatives Judiciary Committee Report on the DNA Identification Act of 1993, at page 10.

DNA samples in the national DNA identification system." The DNA Advisory Board also endorsed the "current level of enforcement of such access and disclosure provisions by the Department of Justice and the FBI and encourages the continuation of such efforts." The DNA Advisory Board's Resolution is contained in Appendix C.

From time to time, the FBI's CODIS Unit may seek guidance on scientific issues affecting the CODIS program (such as partial matches) and may request such assistance from the Scientific Working Group on DNA Analysis Methods (SWGDAM). Other resources for the CODIS Unit are State and Local CODIS Administrators and users who offer feedback to the CODIS Unit during the Annual CODIS Conference and the semi-annual CODIS State Administrators' Meetings.

NDIS Operational Procedures

The responsibilities of the FBI and the NDIS participants are explained in the NDIS Operational Procedures. The FBI, with the involvement of the DNA community, is responsible for determining issues of policy in its administration of the National DNA Index System.

The NDIS Custodian is responsible for ensuring that laboratories participating in NDIS comply with the requirements of Federal law and NDIS Operational Procedures. In accordance with the NDIS Memorandum of Understanding between the Participating Laboratory and the FBI (NDIS MOU), the Designated State Official is responsible for ensuring the compliance of its laboratory and other laboratories in that State with Federal law and NDIS Operational Procedures governing NDIS participation. To the extent possible, all communications and documentation between the FBI and the NDIS participants are provided electronically.

To ensure the reliability, accuracy and compatibility of DNA records uploaded to NDIS, the FBI developed data acceptance standards for the DNA records submitted to the National DNA Index System (see Chapter 4.0 of this Manual). In addition to compliance with the FBI Director's Quality Assurance Standards for Forensic DNA Testing and Databasing Laboratories, NDIS participants must follow the procedures for participating in and uploading DNA records to NDIS.

The NDIS Procedures Board meets several times each year. Board meetings may be conducted in-person or via teleconference. NDIS Procedures Board members vote on issues and/or NDIS operational procedures in-person, via teleconference or by e-mail.

NDIS participating laboratories are subject to assessments conducted by the FBI's CODIS Unit to review a laboratory's compliance with the Federal DNA Identification Act and the NDIS Operational Procedures. The Department of Justice' Office of the Inspector General performs audits of NDIS participating laboratories to review if the "(1) Laboratory was in compliance with the NDIS participation requirements; (2) Laboratory

was in compliance with the Quality Assurance Standards (QAS) issued by the FBI; and (3) Laboratory's forensic DNA profiles in CODIS databases were complete, accurate, and allowable for inclusion in NDIS"; see http://www.justice.gov/oig/reports/codisext.htm for additional information.

Chapter 1.0 Quality Assurance Standards Audit Review

1.1 Quality Assurance Standards - Federal DNA Identification Act

As administrator of the National DNA Index System and in accordance with the Federal DNA Identification Act of 1994 [34 U.S.C. §12592(b)], the FBI is responsible for ensuring that the DNA records in the national index are "generated in accordance with publicly available national standards that meet or exceed the FBI Director's *Quality Assurance Standards for Forensic DNA Testing and DNA Databasing Laboratories.*"

The Federal DNA Act requires that laboratories participating in NDIS "undergo external audits, not less than once every 2 years, that demonstrate compliance with standards established by the Director of the Federal Bureau of Investigation." Additionally, the Federal DNA Act authorizes enforcement of these quality requirements through cancellation of access to NDIS if the quality control standards are not met. *See* 34 U.S.C. §12592(c).

Under the Federal DNA Act, the FBI will review all external QAS audits of laboratories seeking to participate in NDIS and NDIS participating laboratories, to evaluate any findings and determine if further action is warranted. Approved accrediting agencies audit and accredit forensic DNA laboratories for compliance with the FBI Director's QAS.

1.2 Quality Assurance Standards - Audit Requirements

The Federal DNA Act of 1994 [34 U.S.C. §12592(a)(2)] requires compliance with the FBI Director's most recent version of the QAS.

Quality Assurance Standard 15.1 requires that the laboratory conduct an annual audit to determine compliance with the QAS. The qualifications for auditors conducting internal and external QAS audits are described in Standards 15.2 and 15.3 of the Forensic and Databasing QAS. Internal and external audits shall be conducted using the most recent FBI Quality Assurance Standards Audit document(s). QAS Standard 15 audit requirements apply to vendor laboratories used by NDIS participating laboratories as well as NDIS participating laboratories.

All audit documentation shall be retained by the NDIS participating laboratory and be available for inspection during subsequent audits.

1.2.1 Annual Confirmation of Compliance with Audit Requirements

On an annual basis, the CODIS Unit shall notify the State CODIS Administrator of the required reporting for audit certification by the NDIS participating laboratories in that State. It is the State CODIS Administrator's responsibility to ensure the information for that State is submitted by the established deadline.

1.3 Quality Assurance Standards External Audit Review Process

1.3.1 Notification of External Audit and Forwarding of Audit Documents

It is the NDIS participating laboratory's responsibility to arrange and schedule an external QAS audit once every two years³ and to ensure that the audit team is comprised of qualified auditors as required by the QAS.

All external QAS audits of NDIS participating laboratories shall be forwarded to the FBI for review pursuant to this Chapter.⁴ This means that if a laboratory chooses to conduct an external QAS audit each year or multiple external QAS audits in one year, every external QAS audit shall be forwarded to the FBI for review.

As required by Standard 15 of the QAS, it is the NDIS participating laboratory's responsibility to forward the audit report to the CODIS Unit within thirty (30) days of the laboratory's receipt of the report. The NDIS participating laboratory shall include with the audit report all clarifications, responses and corrective action plan/documents, (i.e., revised procedures and/or protocols and their implementation date) [hereinafter referred to as "audit documentation"], necessary for a thorough review of the audit. Any finding(s) challenged by the NDIS participating laboratory shall be clearly indicated as such and appropriate explanation and documentation shall be provided with the audit report. Failure to identify a challenged/contested finding and/or the submission of corrective action(s) for a challenged/contested finding may result in the closure of the audit without consideration of whether the finding was warranted.

All audit documents and related communications shall be submitted to the CODIS Unit in electronic form. The CODIS Unit does not retain the audit documentation submitted by the NDIS participating laboratory.

If the NDIS participating laboratory is unable to forward the corrective action plan/documents within thirty (30) days of its receipt, the NDIS participating laboratory shall submit the audit report and contact the CODIS Unit to request an extension for the submission of the corrective action plan/documents.

1.3.2 NDIS Audit Review Panel(s)

Once the audit documentation is received by the CODIS Unit, the Chair of the NDIS Audit Review Panel shall perform a preliminary review of the documentation to ensure

³ Please see Databasing and Forensic QAS Standard 15 for additional information on the timing of the external QAS audits

⁴ The requirement for an external QAS audit is applicable to each individual mobile laboratory and each individual laboratory in a multi-laboratory state or local system and requires that the audit for each individual laboratory be documented in a separate independent QAS audit document.

that the findings have been addressed and if necessary, follow-up with the NDIS participating laboratory. If the audit does not contain any findings, the review shall be deemed complete and as appropriate, the documentation returned to the NDIS participating laboratory.

Each external QAS audit containing findings shall be reviewed by an NDIS Audit Review Panel. An NDIS Audit Review Panel shall consist of qualified auditors in addition to the Chair: (1) at least two of whom shall be representatives of State or Local forensic DNA laboratories; and (2) at least two of whom shall be representatives of the FBI. The FBI shall designate one Chair who shall serve as the chair of each such Panel and shall have voting privileges.

If the Chair or NDIS Audit Review Panel identifies issues needing clarification, the Chair of the NDIS Audit Review Panel may consult with an auditor, a representative of the agency that performed the audit, or the laboratory, to request clarification or additional information.

The Chair of the NDIS Audit Review Panel shall conclude the review and notify the NDIS Custodian or NDIS Procedures Board, as applicable, in accordance with one of the following:

- (A) Laboratory complied with external QAS audit requirement and the QAS; or
- (B) Laboratory did not comply with external QAS audit requirement and/or the QAS.

If the NDIS participating laboratory complied with the external QAS audit requirement and the QAS, the NDIS Custodian shall close the external QAS audit and notify the NDIS participating laboratory. A laboratory may be found to be in compliance with the external QAS audit and the QAS even though findings were noted in the audit report as long as the corrective action plan/documents appropriately addressed those findings. If the corrective action plan had not been implemented by the completion of the review, a preliminary determination of QAS compliance may be made subject to verification of satisfactory implementation of the corrective action plan. The NDIS Custodian may require that the next regularly scheduled audit of the NDIS participating laboratory be an external QAS audit in order to document compliance with the QAS.

If the NDIS Audit Review Panel found that the laboratory did not comply with the QAS and that such noncompliance has not been remedied, the NDIS Audit Review Panel Chair shall refer the external QAS audit to the NDIS Procedures Board.

1.3.3 NDIS Procedures Board

The NDIS Procedures Board shall review all external QAS audits referred to them by the Chair of the NDIS Audit Review Panel and/or NDIS Custodian.

If the NDIS Procedures Board determines that the NDIS participating laboratory did not

comply with the QAS and that such noncompliance has not been remedied, the NDIS Procedures Board shall provide written notification of its determination to the laboratory director of the NDIS participating laboratory. The laboratory director shall have two weeks to provide the NDIS Procedures Board with a written response to the Board's determination. In the event that the laboratory director does not respond within the requisite time frame, the NDIS Procedures Board shall notify the laboratory director in writing that the participating laboratory's failure to respond will result in suspending that Laboratory's access to NDIS in accordance with the Federal DNA Act. Please refer to Chapter 2.0 on *NDIS Laboratories* for additional information on suspending a laboratory.

If the laboratory director responds and challenges the noncompliance determination, the NDIS Procedures Board shall provide the laboratory director or his/her representative an opportunity to explain the laboratory's position to the NDIS Procedures Board. Within two weeks of the laboratory director's explanation to the Board, the NDIS Procedures Board shall provide the laboratory director with written notification of its decision. The laboratory director may appeal the decision of the NDIS Procedures Board to the Deputy Assistant Director of the FBI Laboratory within two weeks of receiving the decision of the NDIS Board. The decision of the FBI Laboratory Deputy Assistant Director shall be final.

Chapter 2.0 NDIS Laboratories

2.1 National DNA Index System (NDIS) Participation Requirements

The Designated State Official is responsible for collecting all information from laboratories within the State, maintaining copies, and electronically forwarding required documentation to the FBI's NDIS Custodian when requesting participation in NDIS. The Designated State Official shall confirm that he/she represents a criminal justice agency and identify the laboratories in that State proposed for inclusion in NDIS. The NDIS Custodian shall review all communications requesting NDIS participation to ensure that the agency requesting participation is a criminal justice agency. Once the criminal justice agency status of the laboratory is confirmed, the State shall agree to the terms and conditions of the NDIS MOU as well as provide documentation on users and laboratories within the State. Specifically, laboratories seeking to participate or participating in NDIS shall satisfy the following requirements for participation: status as an accredited laboratory; status as a criminal justice agency; status as a laboratory; and expungement of DNA records from NDIS (for databasing laboratories):

Accreditation

Laboratories seeking to participate or participating in NDIS shall be accredited in DNA by a nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic science community; accrediting agencies currently approved by the NDIS Procedures Board include the American Association for Laboratory Accreditation (A2LA) and ANAB (ANSI-ASQ National Accreditation Board). Approved accrediting agencies audit and accredit forensic DNA laboratories for compliance with the FBI Director's QAS.

A mobile laboratory within a state or local system seeking to participate in NDIS shall be accredited in DNA and shall be eligible to participate in NDIS through the CODIS Administrator of its parent laboratory, subject to the approval of the NDIS Custodian.

In a multi-laboratory state or local system, each laboratory that will be generating DNA records for upload to NDIS shall participate in NDIS and shall be accredited in DNA. For a multi-laboratory state or local system, DNA records can be uploaded to NDIS through the parent laboratory or through the individual system laboratory, subject to the approval of the NDIS Custodian.

⁵ Each laboratory must have an Originating Agency Identifier (ORI) number before participating in NDIS. Each State is responsible for obtaining an ORI number by contacting the State Control Terminal Officer and following the policies provided by the Criminal Justice Information Services Advisory Policy Board.

⁶ The American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) and Forensic Quality Services, approved separately as accrediting agencies are now part of ANAB (ANSI-ASQ National Accreditation Board); please refer to the CODIS and NDIS Fact Sheet at http://www.fbi.gov/about-us/lab/biometric-analysis/codis/codis-and-ndis-fact-sheet for an up-to-date listing of accrediting agencies approved by the NDIS Procedures Board.

Criminal Justice Agency

Laboratories seeking to participate or participating in NDIS shall meet the following definition to be considered a criminal justice agency: an agency or institution of the Federal, State, or Local government, other than the office of the public defender, which performs as part of its principal function, activities relating to the apprehension, investigation, prosecution, adjudication, incarceration, supervision or rehabilitation of criminal offenders.

For purposes of participation in the National DNA Index System, the Federal DNA Act was amended by Public Law 106-546 to include the Secretary of Defense as an authorized agency in accordance with 10 U.S.C.§1565.

Laboratory

Laboratories seeking to participate or participating in NDIS shall meet the QAS definition of a laboratory as follows: a facility (1) employing at least two full-time employees who are qualified DNA analysts; and (2) having and maintaining the capability to perform the DNA analysis of forensic and/or casework reference samples, or on database and/or known samples, at that facility.

A contract employee cannot be counted as a full-time qualified DNA analyst for purposes of satisfying the definition of a laboratory.

Expungement

Laboratories seeking to participate or participating in NDIS shall comply with the expungement requirements of Federal law.

The Federal DNA Act requires that States participating in NDIS "shall promptly expunge from that index the DNA analysis (DNA profile) of a person included in the index by that State if the responsible agency or official of that State receives, for each conviction of the person of an offense on the basis of which that analysis (profile) was or could have been included in the index, a certified copy of a final court order establishing that such conviction has been overturned. A court order is not "final" if time remains for an appeal or application for discretionary review with respect to the order." *See* 34 U.S.C. §12592(d)(2).

For States that will be uploading DNA records of arrestees, indicted persons or similar legal specimens, amendments made by the DNA Fingerprint Act of 2005 (P. L. 109-162) require an expungement in the event the charge is dismissed or results in an acquittal or no charge was filed within the applicable time period. NDIS participating States are required to expunge from NDIS the DNA analysis of a person included in NDIS by that State if "the person has not been convicted of an offense on the basis of which that analysis was or could have been included in the index, and the responsible agency or official of that State receives, for each charge against the person on the basis of which the

analysis was or could have been included in the index, a certified copy of a final court order establishing that such charge has been dismissed or has resulted in an acquittal or that no charge was filed within the applicable time period." *See* 34 U.S.C. §12592(d)(2)(A)(ii).

As a condition for participating in NDIS, a laboratory shall have procedures for performing expungements in accordance with the above-referenced Federal law, regardless of whether or not the State DNA law requires expungement.

Prior to the uploading of any arrestee, indicted person or similar legal DNA records to NDIS, the laboratory shall provide the NDIS Custodian with documentation of its expungement procedures. Such documentation shall include the procedures for expunging DNA records from NDIS in accordance with this Chapter as well as any relevant regulation and/or law governing expungement. Once the expungement documentation has been reviewed, the NDIS Custodian shall notify the NDIS participating laboratory if such DNA records may be uploaded to NDIS.

2.2 NDIS Participation and Access

The NDIS Custodian shall review the information submitted by the State and if approved, the State will be provided with the date of activation and documentation of the entry of the laboratory and CODIS users.

A laboratory approved for participation in NDIS is known as an NDIS participating laboratory and is responsible for complying with the Federal DNA Act, the NDIS Privacy Act Notice, the provisions of the NDIS MOU (including the sublicense to use the CODIS software), and these Operational Procedures. The NDIS participating laboratory serving as the designated SDIS for the State is responsible for the State's repository of DNA records collected and maintained under the control of State authorities and is the central point of contact regarding NDIS access for all NDIS participating laboratories in the State. On behalf of the State, the Designated State Official or SDIS shall be responsible for the NDIS participation of the other laboratories in the State and ensuring all such laboratories' adherence to and compliance with the Federal DNA Act, the NDIS Privacy Act Notice and the NDIS MOU.

The sublicense to use the CODIS software granted by the FBI extends to NDIS participating laboratories and their authorized CODIS users who perform forensic DNA analysis only on behalf of criminal justice agencies (or the Secretary of Defense in accordance with 10 U.S.C. §1565) and use the CODIS software in a manner authorized by the FBI. The NDIS participating laboratory shall not use the CODIS software in any manner unless specifically authorized to do so by the FBI. Generally, participation in NDIS and maintenance of a statutorily authorized State DNA database shall be considered an authorized use of the CODIS software. The generation of DNA data and/or a DNA database for dissemination beyond the purposes authorized by the Federal

DNA Act [34 U.S.C. §12592(b)(3)] shall be considered an unauthorized use of the CODIS software. The generation of DNA data and/or a DNA database consisting of such DNA data for dissemination to individuals, entities, agencies or laboratories other than NDIS participating laboratories shall be considered an unauthorized use of CODIS software. Participation in NDIS is subject to accountability and audit. Access to NDIS will be terminated and the NDIS participating laboratory will lose its license to use the CODIS software for failure to abide by the NDIS MOU.

For purposes of NDIS participation, performing forensic DNA analysis for non-criminal justice agencies shall be considered an unauthorized use of the CODIS software; however, forensic DNA analysis may be performed in criminal proceedings provided that (1) the court is ordering the DNA analysis of specific evidence; (2) the evidence being analyzed was obtained in connection with the investigation or prosecution of the Federal/State offense; (3) the evidence being analyzed is in the possession of the Federal/State/Local government, has been subject to a chain of custody, and subject to appropriate storage conditions; and (4) the results of the DNA analysis are provided to the court, the defendant and the Federal/State government. If ordered by the court, the NDIS participating laboratory may upload all eligible DNA records to NDIS.

The NDIS participating laboratory is not authorized to distribute or sublicense the CODIS software, and shall not copy the CODIS software for purposes of distribution or distribute the CODIS software to any person or agency outside the NDIS participating laboratory without the express written permission of the FBI. The NDIS participating laboratory shall not publish or publicly disclose information obtained from or included in the CODIS software and/or NDIS, including, but not limited to: CODIS Bulletins, screen shots of CODIS software, or CODIS meeting, instructional and/or training materials without the prior written approval of the FBI.

Unless specifically noted otherwise, once NDIS participation is approved in writing and access granted, all official communications related to NDIS shall be between the State CODIS Administrator and the NDIS Custodian and/or CODIS Unit.

2.2.1 NDIS Participating Laboratory's Initial Upload of DNA Records

Upon approval of a laboratory's request to participate in NDIS, the laboratory may upload all eligible DNA records to NDIS. Eligible DNA records shall mean the DNA data generated and reviewed by an accredited laboratory that has undergone an external QAS audit that has successfully completed the NDIS Audit Review process in accordance with Chapter 1.0 and that may be searched and stored in NDIS pursuant to Chapters 3.0 and 4.0.

2.3 Add or Change Information about a Laboratory

Once a State is participating in NDIS and the State wishes to add another laboratory, the State CODIS Administrator shall request the addition of another laboratory and provide

information about the laboratory, including documentation of DNA accreditation, the laboratory's most recent external QAS audit, criminal justice agency and laboratory status, and CODIS user information. The CODIS Unit shall review the request and if approved, enter the laboratory information into CODIS.

Occasionally, information about an NDIS participating laboratory changes and the laboratory is responsible for notifying the State CODIS Administrator of those changes. The State CODIS Administrator shall provide the new information to the CODIS Unit which is responsible for making the changes in CODIS.

2.4 Reporting a Laboratory's Change in Status

A laboratory that is participating in NDIS shall report, within five business days, the following change in status to the NDIS Custodian and State CODIS Administrator, as applicable:

- (1) Loss of status as a criminal justice agency;
- (2) Loss, suspension or revocation of accreditation;
- (3) Loss of capability to perform DNA analysis at its facility;
- (4) Loss of DNA technical leader when there is no one in the laboratory who meets the QAS qualifications and is available to serve in that position; and
- (5) Fewer than 2 full-time employees who are qualified DNA analysts.

For the loss of a DNA technical leader or fewer than 2 full time employees who are qualified DNA analysts, the laboratory shall document such notification using the form entitled Contingency Plan Notification Form in Appendix B of the FBI's QAS Audit document.

2.5 Suspension of a Laboratory from NDIS

The NDIS Custodian, Designated State Official, State CODIS Administrator, and Local CODIS Administrator are responsible for ensuring the integrity and accuracy of the DNA records in NDIS. There may be instances, when, as a result of an external audit or other independent action, it is necessary to suspend a laboratory's participation in NDIS until such time as findings or other issues are appropriately addressed. As a result, the NDIS Custodian, Designated State Official, State CODIS Administrator, or Local CODIS Administrator may request/initiate the suspension of a laboratory from NDIS as follows:

- The Designated State Official or State CODIS Administrator (in the event that the request relates to the State laboratory) may request that one of its participating laboratories be suspended.
- A Local CODIS Administrator may request that its laboratory be suspended through, and with the approval of, the State CODIS Administrator.
- The NDIS Custodian may initiate the suspension of a laboratory as a result of that laboratory's external QAS audit, issues identified during an NDIS Participation

Assessment, or if advised of other information that warrants the suspension of that laboratory.

- The NDIS Custodian may initiate suspension of a laboratory if advised of one or more of the following circumstances:
 - o Loss, suspension or revocation of accreditation;
 - o Loss of capability to perform DNA analysis at its facility;
 - Loss of DNA technical leader when there is no one in the laboratory who
 meets the QAS qualifications and is available to serve in that position, and
 there is no contingency plan approved by the FBI;
 - o Fewer than 2 full-time employees who are qualified DNA analysts; or
 - o Failure to comply with the requirement for an external QAS audit.

If the State requests the suspension of a laboratory, the Designated State Official and/or State CODIS Administrator shall request suspension of the laboratory. If the request is approved, the NDIS Custodian shall suspend the laboratory from NDIS participation and confirm the suspension with the Designated State Official and/or State CODIS Administrator.

If the Local Laboratory requests a suspension, the Local CODIS Administrator shall request suspension of the laboratory through the State CODIS Administrator. If the request is approved by the State CODIS Administrator, the NDIS Custodian shall suspend the laboratory from NDIS participation and confirm the suspension with the State CODIS Administrator.

In the event that the NDIS Custodian initiates the suspension of a laboratory, the NDIS Custodian shall notify the laboratory of the suspension and include the reason(s) for such suspension.

DNA records generated by a laboratory during a period of suspension shall not be uploaded to NDIS and may not be eligible for upload to NDIS at the conclusion of the suspension period. The upload of DNA records generated during a laboratory's suspension shall be subject to the approval of the NDIS Custodian.

2.5.1 Appeal of a Suspension Notification by the NDIS Custodian

A laboratory notified of a suspension initiated by the NDIS Custodian may appeal the suspension to the NDIS Procedures Board. Such appeal shall be forwarded to the Chair of the NDIS Procedures Board in writing within two weeks of the laboratory's notification of its suspension. There is no appeal to the NDIS Procedures Board for a suspension requested by the Designated State Official and/or State CODIS Administrator.

The NDIS Procedures Board shall review the documentation submitted by the laboratory and the NDIS Custodian and provide a determination of the appeal within two weeks of their receipt of the appeal documentation. The NDIS Custodian and any NDIS Board

member representing a laboratory that is pursuing an appeal shall not be entitled to vote on the appeal. The determination of an appeal by the NDIS Procedures Board shall be considered a final determination, and the laboratory and State CODIS Administrator as appropriate, shall be notified of such determination.

In the event that the NDIS Procedures Board determines that suspension was not warranted and such suspension is rescinded, all parties notified of the suspension shall be notified of the rescission.

2.5.2 Determination of Status of Suspended Laboratory's DNA Records

The NDIS Custodian is responsible for determining the status of a suspended laboratory's DNA records at NDIS and shall consider the following criteria in making such a determination:

- If the findings noted in the laboratory's external QAS audit would affect the quality of the DNA records generated by that laboratory;
- The time frame for findings noted in the external QAS audit and the amount of DNA records contributed by the suspended laboratory during the relevant period;
- The recommendations of the NDIS Audit Review Panel and/or NDIS Procedures Board, if appropriate;
- The recommendation of the State CODIS Administrator, if appropriate; and/or
- Such other information as deemed appropriate by the NDIS Custodian.

The NDIS Custodian will notify the laboratory of the requirement to remove all or a portion of the laboratory's DNA records from NDIS when notifying the laboratory of its suspension. The removal of DNA records from NDIS is described in Chapter 3.0.

2.5.3 Notification of Suspension of a Laboratory from NDIS

The NDIS Custodian is responsible for notifying the State CODIS Administrator of a laboratory's suspension from NDIS. The State CODIS Administrator is responsible for notifying the relevant criminal justice agencies, as appropriate, of a laboratory's suspension from NDIS. In the event that DNA records are removed, the suspended laboratory, in consultation with the State CODIS Administrator and NDIS Custodian, as appropriate, is responsible for notifying other laboratories that may be affected by the removal of such DNA records.

Requests for information relating to a suspended laboratory will be referred to the State CODIS Administrator. As appropriate, the FBI may confirm the status of a laboratory suspended from NDIS.

2.5.4 Request by Suspended Laboratory to Renew Participation in NDIS

A suspended laboratory may request renewal of its participation in NDIS if the findings/issues identified as the reason for the suspension have been appropriately remediated and/or resolved.

A suspended laboratory seeking to renew its participation in NDIS may address such a request to the NDIS Custodian and include all appropriate documentation, such as external QAS audit documentation containing corrective actions.

The NDIS Custodian is responsible for determining requests by suspended laboratories to renew participation in NDIS. The NDIS Custodian may consult with the State CODIS Administrator, the NDIS Audit Review Panel Chair and the NDIS Procedures Board, as appropriate, in determining whether a suspended laboratory may renew its participation in NDIS. The NDIS Custodian may also impose conditions on a suspended laboratory's participation in NDIS, such as undergoing an external QAS audit to document compliance with corrective actions.

If the NDIS Custodian approves a suspended laboratory's request for participation in NDIS and that laboratory had removed all or a portion of its DNA records from NDIS, the NDIS Custodian shall advise the laboratory if such DNA records can be uploaded to NDIS. The NDIS Custodian may impose conditions on the uploading of DNA records from a previously suspended laboratory, such as requiring that such records be reviewed by a qualified DNA analyst from another NDIS participating laboratory.

If the NDIS Custodian denies a request by a suspended laboratory to participate in NDIS, the suspended laboratory may appeal that determination to the Deputy Assistant Director of the FBI Laboratory. The laboratory's appeal shall be in writing and commenced within two weeks of receipt of the denial by the NDIS Custodian. The Deputy Assistant Director shall have two weeks to determine the appeal and the decision of the Deputy Assistant Director shall be final.

2.6 CODIS Administrator

The State and Local CODIS Administrators (hereinafter referred to as "CODIS Administrator") are the central points of contact between the NDIS participating laboratory and the NDIS Custodian and/or CODIS Unit.

The CODIS Administrator shall meet the educational and experience qualifications specified in the FBI Director's *QAS*.

The CODIS Administrator shall have successfully completed the FBI's QAS auditor training within one (1) year of assuming the CODIS Administrator role or position. If the CODIS Administrator has already successfully completed the FBI's QAS auditor training on the FBI Audit document, no additional QAS auditor training shall be required.

However, it is strongly recommended that the CODIS Administrator complete the FBI's QAS auditor training on the current FBI Audit document.

The CODIS Administrator shall also have successfully completed the CODIS software training sponsored by the FBI within six months of assuming the Administrator role or position. If the CODIS Administrator has already successfully completed the CODIS software training on the current version of CODIS software in effect, no additional CODIS software training shall be necessary. The CODIS Administrator shall complete additional CODIS training as required by the CODIS Unit if notification of such additional CODIS training is provided by the CODIS Unit.

The CODIS Administrator shall obtain and maintain the FBI security access required to become a CODIS user and successfully complete the annual training described in this Chapter.

2.6.1 Designation of Alternate CODIS Administrator

An Alternate CODIS Administrator shall be designated to fulfill the CODIS Administrator role when the CODIS Administrator is absent or unavailable. An Alternate CODIS Administrator shall be designated within ninety (90) days of a vacancy in the Alternate CODIS Administrator position.

Any Alternate CODIS Administrator designated after June 1, 2018 shall meet the educational and experience qualifications of a CODIS Administrator specified in the FBI Director's *QAS*.

The Alternate CODIS Administrator shall have successfully completed the FBI's QAS auditor training within one year of assuming the Alternate CODIS Administrator role or position. If the Alternate CODIS Administrator has already successfully completed the FBI's QAS auditor training on the FBI Audit document, no additional QAS auditor training shall be required. However, it is strongly recommended that the Alternate CODIS Administrator complete the FBI's QAS auditor training on the current FBI Audit document.

The Alternate CODIS Administrator shall have successfully completed the CODIS software training sponsored by the FBI within six months of assuming the Alternate CODIS Administrator role or position. If the Alternate CODIS Administrator has already successfully completed the CODIS software training on the current version of CODIS software in effect, no additional CODIS software training shall be necessary. The Alternate CODIS Administrator shall complete additional CODIS training as required by the CODIS Unit provided that notification of such additional CODIS training is provided by the CODIS Unit.

The Alternate CODIS Administrator shall obtain and maintain the FBI security

access required to become a CODIS user and successfully complete the annual training described in this Chapter.

2.6.2 CODIS Administrator – Attendance at Meetings and Training

A State CODIS Administrator or his/her Alternate shall attend the regularly scheduled annual CODIS Conference and semi-annual State Administrators meetings' sponsored by the FBI or seek an excused absence from the NDIS Custodian if neither the State CODIS Administrator nor the Alternate State CODIS Administrator can attend.

A CODIS Administrator or his/her Alternate shall attend a scheduled annual CODIS Conference sponsored by the FBI or seek an excused absence from the NDIS Custodian if neither the CODIS Administrator nor the Alternate CODIS Administrator can attend.

The request for an excused absence shall be in writing and signed by the Laboratory Director of the NDIS participating laboratory.

2.6.3 CODIS Administrator - General Responsibilities

The CODIS Administrator⁷ is the central point of contact in the laboratory for CODIS and serves as the gatekeeper for the DNA records entered into CODIS. As part of his/her gatekeeper function, the CODIS Administrator is responsible for performing, or overseeing the performance of, the following, as applicable:

- Notify State CODIS Administrator of Add/Remove/Update CODIS user information
- Ensure that CODIS user(s) successfully complete the required annual training
- Notify the NDIS Custodian, within five (5) business days, of the following:
 - If a CODIS user, CODIS IT user or CODIS SEN user in its laboratory has been arrested for, or convicted of, a criminal offense
 - If the laboratory loses its criminal justice agency status
 - If the laboratory loses its accreditation, has its accreditation suspended or has its accreditation revoked
 - If the laboratory loses the capability to perform DNA analysis at its facility
 - If the laboratory has fewer than two full-time employees who are qualified DNA analysts
 - If the laboratory has a vacancy in the laboratory's Technical Leader position when there is no one in the laboratory who meets the Quality

⁷ For purposes of these Procedures, references to a CODIS Administrator include the Alternate CODIS Administrator or his/her designee.

Assurance Standards' qualifications and is available to serve in that position

- If the laboratory is not in compliance with the external QAS audit requirement
- Review and/or approve, as appropriate, protocols or procedures for the entry, searching, match resolution and retention of DNA records in the state/local DNA database(s), including those categories of DNA records that are not uploaded to NDIS
- Compliance with CODIS security requirements
- Compliance with QAS Standard 17
- Ensure NDIS specimen eligibility is determined by CODIS users
- Upload of DNA records to SDIS and NDIS (schedule uploads from local laboratories) and review of CODIS generated reports
- Backup of CODIS data (including performance of periodic restores to ensure backups are working properly)
- Review and make best efforts to Disposition Matches in accordance with Chapter 6.0 on *Confirmation and Hit Dispositioning*
- Review of all CODIS materials and changes to NDIS Operational Procedures, and implementation, if applicable
- Compilation and monthly reporting of Investigations Aided and Hit Statistics to SDIS and/or NDIS
- Completion of the Annual Audit certification

2.6.4 CODIS Administrator - Reporting Responsibilities

CODIS Administrators shall report to their State CODIS Administrator and State CODIS Administrators shall be responsible for reporting to the NDIS Custodian and/or CODIS Unit. Additionally, issues involving NDIS at the local level should be addressed to the State CODIS Administrator for resolution before contacting the NDIS Custodian.

2.6.5 State CODIS Administrator

The State CODIS Administrator has additional responsibilities for a State's participation in NDIS which include serving as the central point of contact with the NDIS Custodian and ensuring other participating laboratories in that State comply with the terms and conditions of the NDIS MOU. The State CODIS Administrator is responsible for advising and instructing Local CODIS Administrators of their responsibilities for participation in NDIS. Additionally, the State CODIS Administrator is responsible for reconciling match dispositions within his/her State.

The State CODIS Administrator is responsible for ensuring that all information about the laboratories participating in that State are communicated to the NDIS Custodian and/or CODIS Unit. The State CODIS Administrator may transmit (on behalf of the Designated State Official) any of the required correspondence, documentation, or paperwork.

Additionally, State CODIS Administrators and CODIS Administrators for Databasing Laboratories are responsible for having documented procedures for the State or laboratories that address the following:

- Expungement of DNA Records
- Confirmation of an Intrastate Candidate Match
 - o Include requirement for best effort to resolve matches within 30 business days
 - Release of information when a non-qualifying offender is involved in the candidate match
- Uploads to SDIS, if applicable
- Categories of DNA Records Eligible for the State DNA Index System
- Access to DNA Records and DNA Samples in the State DNA Index System

2.7 CODIS User

A *CODIS user* is a government employee who: (1) has login access to the CODIS (i.e., State or Local) system and is authorized to read, add, modify or delete DNA records in CODIS; or (2) is a qualified DNA analyst responsible for producing the DNA profiles stored in NDIS.

There are three additional categories of CODIS users that are required to be cleared at NDIS although they are not authorized to add, modify or delete DNA records in CODIS: (1) CODIS Contract user; (2) CODIS Information Technology (IT) user; and (3) CODIS Shared Enterprise Network (SEN) user. CODIS user, CODIS IT user and CODIS SEN user must undergo an FBI security check and maintain a security clearance while holding such designations.

A qualified DNA analyst at a vendor laboratory who is responsible for DNA records stored in NDIS may be added to NDIS as a CODIS Contract user. Because this user does not have physical access to CODIS, the user does not require an FBI security check, although a State may perform its background or security investigation on this category of users. A CODIS Contract user is not authorized to add, modify or delete DNA records in CODIS.

An IT employee of an NDIS participating laboratory or an IT contractor working on-site at the NDIS participating laboratory or its supervisory criminal justice agency who is permitted access to CODIS for computer hardware/software and telecommunications

maintenance purposes may be added to NDIS as a CODIS IT user. Because this user has physical access to CODIS, an FBI security check is required (in addition to any security check performed by the employing governmental agency). A CODIS IT user is not authorized to add, modify or delete DNA records in CODIS

A designated employee of an NDIS participating laboratory who requires access to the CODIS network in order to perform his/her job may be granted access to the CODIS network as a CODIS SEN user. Such access may be granted at the discretion of the FBI. Because this user has physical access to the network, an FBI security check is required (in addition to any security check performed by the employing governmental agency). A CODIS SEN user is not authorized to add, modify or delete DNA records in CODIS.

A contract employee working as a qualified DNA analyst for an NDIS laboratory shall be processed as a CODIS user (and not a CODIS Contract user). Similarly, an IT contractor working on-site at the NDIS participating laboratory or its supervisory criminal justice agency who has login access to the CODIS system for computer hardware/software and telecommunications purposes shall be processed as a CODIS IT user (and not a CODIS Contract user).

2.7.1 Process to Become an Approved CODIS User, CODIS IT User, CODIS SEN User or CODIS Contract User

To add a CODIS user, CODIS IT user or CODIS SEN user to NDIS, the CODIS Administrator shall forward a request to the CODIS Unit with required security forms. The CODIS Unit will review the application and if complete, initiate a security check on the prospective CODIS user, CODIS IT user, or CODIS SEN user.

For a CODIS user, once the CODIS Unit is notified that the individual has passed the FBI's security check, the individual will be processed as a CODIS user in training in accordance with Section 2.7.2.

For a CODIS IT or CODIS SEN user, once the CODIS Unit is notified that the individual has passed the FBI's security check, the CODIS Administrator shall be notified that the individual has been approved as a CODIS IT or CODIS SEN user. A CODIS IT or CODIS SEN user employed by a multi-laboratory system and who has been approved by the FBI's CODIS Unit can be added as a CODIS IT or CODIS SEN user to all the laboratories in the system.

To add a CODIS Contract user, the CODIS Administrator will forward a request that includes required information to the CODIS Unit. If approved by the CODIS Unit, the CODIS Contract user shall be added to NDIS and the CODIS Administrator shall be notified that the individual has been approved as a CODIS Contract user.

Occasionally, information about a CODIS user, CODIS Contract user, CODIS IT user or

CODIS SEN user will change (i.e., a name change resulting from a change in marital status). In the event of such a change, the CODIS Administrator shall forward a request to the CODIS Unit that includes the updated information and required supporting documentation.

2.7.2 Approval of Prospective CODIS User to Access CJIS SEN for Training Purposes

The CODIS Administrator is responsible for ensuring that only authorized CODIS users are permitted access to CODIS and/or the CODIS network. Once notified that a prospective CODIS user has passed the FBI's security check, the CODIS Unit shall establish a user account in the CODIS training database. The CODIS Administrator shall be notified that the individual has been cleared to take the Annual Review of DNA Data Accepted at NDIS (annual training). A CODIS user in training may have read only access to CODIS and the network for training purposes but shall not be authorized to enter, add, modify or delete any DNA records in CODIS until added as an approved CODIS user at NDIS.

The individual shall not be approved as a CODIS user at NDIS until the successful completion of the annual training.

2.7.3 Approved CODIS User at NDIS

Upon successful completion of the annual training, the prospective CODIS user shall be added as a CODIS user to NDIS and the CODIS Administrator shall be notified of the approval of the CODIS user.

2.7.4 Annual Training for CODIS Users

CODIS users determine the specimen eligibility of DNA records for CODIS and NDIS. On an annual basis, in accordance with a schedule determined by the NDIS Custodian, the CODIS Administrator shall ensure that each CODIS user (who: (1) has login access to the CODIS (i.e., State or Local) system and is authorized to read, add, modify and delete DNA records in CODIS; or (2) is a qualified DNA analyst responsible for producing the DNA profiles stored in NDIS and contract employee working as a qualified DNA analyst for an NDIS laboratory, successfully completes the annual training. This annual training includes refresher training on specimen eligibility of DNA records for NDIS.

CODIS Contract, CODIS IT and CODIS SEN users are not authorized to add, modify or delete DNA records in CODIS and therefore are not required to complete this annual training.

The NDIS Custodian shall establish a schedule for completion of the annual training.

Any CODIS user who has not successfully completed the required annual training in accordance with this schedule shall be denied access to enter DNA records into CODIS until completion of the required annual training.

2.7.5 Removal of a CODIS User

For purposes of this section, the reference to CODIS user shall also include CODIS Contract, CODIS IT and CODIS SEN users.

A CODIS Administrator may request the removal of a CODIS user for the following, but not limited to, circumstances:

- (1) The CODIS user may have a name change due to a change in marital status.
- (2) The CODIS user may leave employment at a participating laboratory or a change in job status makes it inappropriate to continue to access NDIS.
- (3) The CODIS user may fail a periodic FBI security check and the FBI's rejection of the security check would require the State to remove the user.
- (4) There may be a quality issue with the DNA records associated with the CODIS user.

Removal of the CODIS user may be initiated by either the State or the NDIS Custodian.

If any of the above circumstances occur, the CODIS Administrator shall request the removal of the CODIS user within 30 days. In the event of a removal for reasons described in subsections (3) and (4) above, the CODIS Administrator shall also make a recommendation on whether the DNA records associated with the CODIS user should be removed from NDIS. The CODIS Administrator shall forward a request to the CODIS Unit for removal of the CODIS user. If the removal of a CODIS user is initiated by the NDIS Custodian, the CODIS Administrator shall be notified and as appropriate, provide a recommendation on the disposition of the DNA records associated with the CODIS user.

2.7.5.1 Removal of DNA Records from NDIS Associated with a CODIS User

If deemed necessary, removal of the DNA records associated with a CODIS user shall be performed by the CODIS Administrator in accordance with Chapter 3.0. The State CODIS Administrator shall notify the NDIS Custodian of the removal of the CODIS user and the user's DNA records.

Chapter 3.0 DNA Records

3.1 DNA Records Accepted at NDIS

The Federal DNA Act specifies the categories of DNA records that may be stored and searched in the National DNA Index System (NDIS).

3.1.1 Forensic/Offender DNA Records

In accordance with the Federal DNA Act, the following categories of forensic/offender DNA records may be stored and searched in NDIS:

Specimen Category	Definition
Arrestee	The known sample from a person who has been arrested and in accordance with the law of the applicable jurisdiction is required to provide a DNA sample for analysis and entry into a state DNA database. The term "arrestee" includes persons who have been charged in a formal criminal instrument, such as an indictment or an information.
Convicted Offender	The known sample from a person who has been convicted of a Federal, Military or State qualifying offense in a jurisdiction that requires that persons convicted of enumerated crimes or qualifying offenses provide a DNA sample for analysis and entry into a Federal, Military or State DNA database.
Detainee	The known sample from a non-United States (U.S.) person detained under the authority of the U.S. and required by law to provide a DNA sample for analysis and entry into a State/national DNA database.
Forensic Mixture	A specimen category in the CODIS software that is stored in the Forensic Mixture Index and originates from a forensic sample (biological sample found at the scene of a crime) that contains DNA contributed from more than one source attributable to a putative perpetrator(s).
Forensic Partial	A specimen category in the CODIS software that is stored in the Forensic Partial Index and originates from a single source (or a fully deduced profile originating from a mixture) Forensic Sample attributable to the putative perpetrator with either locus or allelic dropout at any of the 13 Original CODIS Core Loci.
Forensic Targeted	A specimen category in the CODIS software that is stored in the Forensic Targeted Index and originates from a forensic partial or a forensic mixture that does not meet the NDIS moderate match estimate threshold of 1 in 10 million, but does meet the match rarity estimate threshold of 1 in 10 million if searched at a specified stringency by locus (high or moderate).

Forensic Unknown	A specimen category in the CODIS software that is stored in the Forensic Index and originates from a single source (or a fully deduced profile originating from a mixture) Forensic Sample attributable to the putative perpetrator and contains results for all 13 Original CODIS Core Loci.
Juvenile	The known sample from a juvenile (as that term is defined by
	the relevant jurisdiction) who is required by State law to provide
	a DNA sample for analysis and entry into a State DNA database.
Legal	The known reference sample from a person whose DNA sample
	is collected under applicable legal authorities (State law),
	provided that DNA samples that are voluntarily submitted solely
	for elimination purposes shall not qualify as a Legal specimen.
Multi-allelic Offender	An offender (arrestee, convicted offender, detainee or Legal
	Index specimen) DNA record having three or more alleles at two
	or more loci.

States seeking to upload Arrestees, Detainees and Legal DNA records shall request approval to upload these specimen categories from the CODIS Unit. Such request shall include the applicable legal authority for collecting and databasing the Arrestee, Detainee and Legal DNA records and the relevant expungement procedures; the requirement for expungement is explained further in Chapter 2.0 on *NDIS Laboratories*.

In accordance with the Federal DNA Act, the DNA records from persons who voluntarily submitted DNA samples solely for elimination purposes ('elimination' specimen category) shall not be included in NDIS. In accordance with this prohibition, victim DNA records are not authorized or eligible to be uploaded to or searched at NDIS.

3.1.1.1 Eligibility of DNA Records for Forensic Indexes at NDIS

In determining the eligibility of a DNA record for the Forensic Indexes (Forensic Mixture, Forensic Partial and Forensic Unknown) at NDIS, there shall be documentation of the following three criteria:

- (1) That a crime has been committed;
- (2) That demonstrates the DNA sample was recovered directly from the crime scene and is attributed to the putative perpetrator; and
- (3) That elimination sample(s) have been requested, if applicable.

Eligibility for uploading DNA records to NDIS is determined by a CODIS user who has successfully completed the Annual Review of DNA Data Accepted at NDIS. Pursuant to the Privacy Act Notice for NDIS (Appendix B), the NDIS Custodian has the authority to determine if certain DNA records contributed to NDIS are eligible for upload to NDIS and if uploaded, the NDIS Custodian may determine if certain DNA records should be deleted based upon a review of the facts and consultation with the CODIS user. The

NDIS Custodian's determination of eligibility shall be final.

Criteria 1: Documentation that a crime has been committed.

In most cases, a case number, case report or other indicia of a criminal investigation may serve as documentation that a crime has been committed. If the applicable law enforcement agency has determined that a crime has not been committed (sometimes referred to as "unfounded"), then this criteria cannot be satisfied and the resulting DNA record(s) is not eligible for NDIS.

Victim Consent

In determining whether a crime has been committed, some jurisdictions require that the victim consents to the forwarding of the sexual assault evidence kit to the law enforcement agency or forensic laboratory. If the victim files a criminal complaint consenting to the forwarding of the kit to the law enforcement agency and laboratory, and the resulting forensic DNA record(s) otherwise satisfies the NDIS criteria (QAS, request for elimination samples, as applicable), then the DNA record(s) generated from the kit is eligible for NDIS.

Some jurisdictions authorize anonymous/blind or third-party reporting (by a designated health care professional), in which a number is assigned to the sexual assault evidence kit and the kit is then processed by law enforcement as a criminal case. In those jurisdictions, that reporting mechanism may be deemed sufficient documentation of the initiation of the criminal investigation. Under those circumstances, a jurisdiction must have available documentation, such as a case report or other indicia of the criminal investigation and, victim consent, if applicable, to satisfy the criteria for NDIS eligibility for that forensic DNA record.

In jurisdictions without blind or third-party reporting where the sexual assault kit is processed without the victim's consent, the statutory mandatory testing requirement may be sufficient documentation of the criminal investigation in accordance with that jurisdiction's law for the forensic DNA record(s) to be deemed NDIS eligible. Under those circumstances, a jurisdiction must have available documentation, such as a case report or other indicia of the criminal investigation to satisfy the criteria for NDIS eligibility.

Criteria 2: Documentation that the DNA sample was recovered directly from the crime scene and attributable to the putative perpetrator.

The Forensic Indexes contain DNA records obtained from forensic samples recovered directly from the crime scene, the victim (such as a sexual assault evidence kit, see below for additional detail), or the victim's clothing, and are attributable to the putative perpetrator. Forensic unknown, forensic mixture or forensic partial DNA records from solved and unsolved cases are eligible for upload to NDIS. For cases in which the identity of the putative perpetrator is known, it is important to ensure that the DNA

profile is developed from crime scene evidence and not from samples independent of the crime/crime scene.⁸

Suspect DNA Records

For purposes of NDIS eligibility, an item taken directly from a suspect shall generally not be considered a forensic sample but shall be considered as a suspect or deduced suspect sample. An item for which the suspect's profile could reasonably be expected to be found that is taken from the crime scene or is part of the crime scene independent of the crime (e.g., suspect's car) are examples of suspect or deduced suspect DNA records that are not eligible for NDIS. Suspect samples also include:

- DNA samples taken from a suspect;
- Items taken directly from the suspect (e.g., clothing); or
- Items in the suspect's possession (e.g., backpack being worn by suspect, suspect's home, suspect's car).

Items of evidence collected directly from the suspect in connection with criminal possession offenses may be difficult to categorize for NDIS eligibility purposes. For example, a swabbing of a gun taken directly from the suspect or an item the suspect is wearing (e.g., clothing, backpack) is considered a deduced suspect sample and thus, is not eligible for NDIS. While this evidence may be probative in proving a central element of the criminal possession offense, the sample is not a forensic unknown for NDIS eligibility purposes.

While the defendant's possession of an item may appear to resolve the eligibility issue, documentation of the scene of the crime or the item's use in the commission of the crime are important factors to consider in determining a DNA record's eligibility for upload to NDIS and why suspect samples are qualified as 'generally' not eligible for NDIS. Additionally, if a State has a DNA database collection law that authorizes the inclusion of suspect DNA records in its State DNA database, the State may request approval to upload these suspect DNA records to the Legal Index at NDIS in accordance with Section 2.1.

Sexual Assault Evidence Kits

In most cases, the non-victim DNA profile(s) derived from a sexual assault evidence kit is eligible for NDIS if there is documentation that a crime has been committed and that, if there were any consensual partners, elimination samples have been provided or requested from those individuals. In circumstances where the identity of the putative perpetrator is known, it is important to ensure that the DNA profile is developed from crime scene evidence and not from samples independent of the crime/crime scene, such as suspect or deduced suspect samples which are not generally eligible for NDIS (see footnote 8).

⁸ DNA samples from known suspects that are collected independent from the crime/crime scene are considered suspect or deduced suspect DNA records; as such, they are not generally eligible for NDIS unless State law authorizes the collection and databasing of suspect samples and the FBI's CODIS Unit has approved the State to upload such as Legal DNA record(s) to NDIS.

Criteria 3: Documentation that elimination samples have been requested, if applicable.

To ensure that only those DNA record(s) relating to a putative perpetrator are uploaded to NDIS, elimination samples, if applicable, shall be requested and the request documented. An example of an elimination sample is the homeowner of a house that has been burglarized. Another example is a consensual partner in a sexual assault case when the victim indicates that he/she engaged in consensual sexual relations close in time to the occurrence of the sexual assault. Under these circumstances, law enforcement officials should request and document consent for a DNA sample from these individuals in order to eliminate that individual's DNA profile from consideration as the forensic DNA record(s)⁹ developed from the evidence. Only if the elimination sample has been requested by the laboratory and that request documented may the forensic DNA record(s) be uploaded to SDIS and NDIS. That is because the Federal DNA Act [34 U.S.C. §12592(a)(1)(C)] prohibits the inclusion of DNA records at NDIS that are voluntarily submitted solely for elimination purposes. In the event that the elimination sample obtained from the individual (homeowner or consensual partner in the above examples) is matched to the evidence (forensic DNA record), that forensic DNA record must be removed from NDIS and the removal documented.

3.1.1.2 DISC-Enabled Forensic Unknown DNA Records

Forensic unknown DNA records for unsolved homicide, rape/sexual assault, kidnapping and terrorism cases may be designated by an NDIS participating laboratory for searching against rapidly enrolled arrestee DNA records. These designated forensic unknown DNA records are enabled for the DNA Index of Special Concern (DISC).

An NDIS participating laboratory having DISC-enabled forensic unknown DNA records shall be responsible for the following:

- Disposition Rapid DNA hits within a maximum of three business days of the hit notification; and
- Documented follow up on an Unsolicited DNA Index of Special Concern Notification (UDN) to ensure that the Submitting Law Enforcement Investigative Agency is aware of that hit within a maximum of three business days of issuance of the UDN.

3.1.2 Missing Person-Related DNA Records

In accordance with the Federal DNA Act, the following categories of DNA records may

⁹ Forensic DNA record(s) for these purposes includes forensic mixture, forensic partial and forensic unknown DNA records.

be stored and searched in the Missing Person's component of NDIS:

Specimen Category	Definition
Biological Child	The known reference sample voluntarily provided by an
	adult child or provided with the parental/guardian consent
	for a minor child of a reported missing person.
Biological Father	The known reference sample voluntarily provided by the
	biological father of a reported missing person.
Biological Mother	The known reference sample voluntarily provided by the
	biological mother of a reported missing person.
Biological Sibling	The known reference sample voluntarily provided by the
	full or half biological adult sibling or provided with the
	parental/guardian consent of a full or half biological minor
	sibling of a reported missing person.
Deduced Missing Person	Considered a reference sample of a reported missing person
	that has been generated by examining intimate items
	purported to belong to the missing person such as a
	toothbrush, and compared to close biological relatives, if
N. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.	possible.
Maternal Relative	The known reference sample voluntarily provided by a
	maternal biological relative who is not a mother, child or
M D	sibling of a reported missing person.
Missing Person	The known reference sample from an individual that is
Paternal Relative	missing. The Impayor reference compile vely interity may ided by a
Paternal Relative	The known reference sample voluntarily provided by a paternal biological relative who is not a father, child or
	sibling of a reported missing person.
Spauga	The known reference sample voluntarily provided by a
Spouse	presumptive parent of a common child.
Unidentified Person	The DNA profile developed from the recovered deceased
Officentified I cisuil	(including body parts and tissue) or an individual who is
	unidentified (e.g., children who cannot and others who
	cannot or refuse to identify themselves).
	cumot of refuse to identify themselves).

3.2 DNA Indexes at NDIS

Following are the DNA Indexes at NDIS. The searching of these DNA Indexes is described in Section 5.1.

Forensic and Offender-Related Indexes with Applicable Specimen Categories

Arrestee Index	Convicted Offender Index	Detainee Index	DNA Index of Special Concern ¹⁰	Forensic Mixture Index	Forensic Partial Index	Forensic Targeted Index	Forensic Unknown Index	Legal Index	Multi- allelic Offender Index
Arrestee	Convicted Offender	Detainee	DISC- enabled Forensic Unknown	Forensic Mixture	Forensic Partial	Forensic Targeted	Forensic Unknown	Legal	Multi- allelic Offender
	Juvenile								

Missing Person-Related Indexes with Applicable Specimen Categories

Relatives of Missing Person Index	Spouse Index	Unidentified Human (Remains) Index	Missing Person Index	Pedigree Tree Index
Biological	Spouse	Unidentified	Deduced	Deduced
Child		Person	Missing	Missing
			Person	Person
Biological			Missing	Missing
Father			Person	Person
Biological				Biological
Mother				Child
Biological				Biological
Sibling				Father
Maternal				Biological
Relative				Mother
Paternal				Biological
Relative				Sibling
				Maternal
				Relative
				Paternal
				Relative
				Spouse

¹⁰ The DNA Index of Special Concern or DISC consists of forensic unknown DNA records designated by the NDIS participating laboratory and developed from unsolved homicide, rape/sexual assault, kidnapping and terrorism cases, which will be searched against rapidly enrolled arrestee DNA records.

3.3 All DNA Records

A laboratory's failure to comply with the categories of DNA records acceptable at NDIS as described in Sections 3.1.1 and 3.1.2 may result in the suspension or termination of that laboratory's access to NDIS in accordance with the Federal DNA Act.

A DNA record that is stored in NDIS includes the following information:

- (A) the DNA profile;
- (B) the NDIS Agency identifier for the submitting agency (Laboratory ORI #);
- (C) the NDIS Specimen Identification Number; and
- (D) the DNA personnel associated with/assigned to the DNA analysis.

No personally identifiable information relating to the donor, such as name, date of birth¹¹, social security number, or criminal history record number, is included in a DNA record stored at NDIS. It should be noted that no DNA samples are stored at NDIS.

3.4 Federal DNA Act Limits Access to DNA Records and DNA Samples

The Federal DNA Act provides that the National DNA Index System "shall include only information on DNA identification records and DNA analyses that are maintained by Federal, State, and local criminal justice agencies (or the Secretary of Defense in accordance with section 1565 of title 10, United States Code) pursuant to rules that allow disclosure of *stored DNA samples and DNA analyses* only--

- (A) to criminal justice agencies for law enforcement identification purposes;
- (B) in judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules;
- (C) for criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged; or
- (D) if personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes." [34 U.S.C.§12592(b)(3)]

The unauthorized disclosure of individually identifiable DNA information stored in the National Index is punishable by a fine not to exceed \$100,000 (34 U.S.C. §12593(c)(1)). Obtaining DNA samples or DNA information, without authorization, is punishable by a maximum fine of \$250,000 or imprisonment for not more than one year or both fine and imprisonment (34 U.S.C. §12593(c)(2)). A laboratory's access to NDIS is subject to cancellation for noncompliance with these privacy requirements. The privacy

¹¹ Available metadata, such as the date of birth, may be included in missing person records stored at NDIS.

requirements are applicable to NDIS participating laboratories by Federal law [34 U.S.C. §12592] and through the NDIS MOU.

The NDIS participating laboratory is responsible for compliance with the limited access and disclosure of DNA samples and DNA analyses required by the Federal DNA Act. While States may have DNA database laws that appear to permit more access to the DNA data, if that State is a participant in the National DNA Index System, the State agrees to abide by, and comply with, the more restrictive provisions contained in the Federal DNA Act by agreeing to the NDIS MOU.

The NDIS participating laboratory shall not provide access to or disclosure of DNA records that have been uploaded to NDIS to an individual, entity, agency, or laboratory that is not a criminal justice agency nor authorized to access such DNA records under the Federal DNA Act. If the NDIS participating laboratory disseminates, provides, or releases any or all of its DNA records that have been uploaded to NDIS for purposes not authorized under the Federal DNA Act or to an individual, entity, agency, or laboratory other than another NDIS participating laboratory, the NDIS participating laboratory shall notify the FBI and remove those DNA records from NDIS.

As noted in the Introduction, recommendations from the Federal DNA Advisory Board have also shaped the administration of the National DNA Index System. In the House of Representatives Judiciary Committee Report on predecessor legislation, the DNA Identification Act of 1993, the Committee explained its expectations that the DNA Advisory Board "also advise the Director on other scientific and policy questions relating to forensic applications of DNA. In particular, it would be appropriate for the Board to address: (1) the statistical, and population genetics issues that have been raised; and (2) the privacy, law enforcement and technical issues associated with the FBI's program to establish a databank of DNA profiles, known as CODIS."12 Pursuant to this legislative direction and its charter, the DNA Advisory Board considered standards for acceptance of DNA profiles in CODIS which take account of relevant privacy, law enforcement and technical issues and endorsed the "current level of enforcement of such access and disclosure provisions by the Department of Justice and the FBI and encourages the continuation of such efforts." The DNA Advisory Board also endorsed the interpretation of the Federal DNA Act to limit access of the anonymous DNA data to criminal justice agencies for a population statistics database, forensic identification, forensic research, forensic protocol development or quality control purposes. 13

NDIS participating laboratories are also responsible for complying with their applicable State law concerning access to the DNA data in their State DNA database, especially if those provisions are more restrictive than the Federal DNA Act.

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¹² House Report 103-45, House of Representatives Judiciary Committee Report on the DNA Identification Act of 1993, at page 10.

¹³ The DNA Advisory Board's Resolution is contained in Appendix C.

3.4.1 FBI Quality Assurance Standards Require Confidentiality

Standard 11 of the FBI's QAS require confidentiality for reports, case files, DNA records and databases, unless otherwise provided by Federal or State law. The QAS require that laboratories have procedures "for the release of personally identifiable information in accordance with applicable State and Federal law" and "to ensure the privacy of reports, case files, DNA records and databases." Forensic QAS Standards 11.3.3 and 11.3.1 and Databasing QAS Standard 11.3.2.

3.4.2 Responsibility for DNA Records

A DNA record entered into CODIS shall be considered the exclusive property and sole responsibility of the NDIS participating laboratory that enters such record into CODIS. Pursuant to the Privacy Act Notice for NDIS, these "DNA records generated by criminal justice agencies, together with the personally identifiable information of DNA personnel, shall be retained in NDIS as long as they are substantiated by internal records of the submitting agency and are permitted either by consent, by judicial/criminal justice authority, or by Federal, State, or local law," and further, "[a]gencies granted access to NDIS are required to establish and maintain a system of controls to ensure that continued use of their DNA records in NDIS is lawfully permitted." 61 Fed. Reg. No. 139 (July 18, 1996); see Appendix B.

Participation in NDIS requires adherence to the Federal DNA Act, which requires that access to and disclosure of stored DNA samples and analyses be limited to the authorized purposes expressed in that law. Accordingly, NDIS participating laboratories shall not provide access to or disclosure of DNA records that have been uploaded to NDIS to an individual, entity, agency, or laboratory that is not a criminal justice agency nor authorized to access such DNA records under the Federal DNA Act. If the NDIS participating laboratory disseminates, provides, or releases any or all of its DNA records that have been uploaded to NDIS for purposes not authorized under the Federal DNA Act or to an individual, entity, agency, or laboratory other than another NDIS participating laboratory, the NDIS participating laboratory shall notify the FBI and remove those DNA records from NDIS. Additionally, the generation of DNA data and/or a DNA database consisting of such DNA data for dissemination to individuals, entities, agencies or laboratories other than NDIS participating laboratories shall be considered an unauthorized use of the CODIS software.

3.4.3 Access by Participating Criminal Justice Agencies

In accordance with the Federal DNA Act, disclosure of DNA records at NDIS is authorized for law enforcement identification purposes to the Federal, State and Local criminal justice agencies who participate in NDIS.

3.4.4 Access by Defendant to DNA Records at NDIS

In accordance with the Federal DNA Act, a defendant may have access to the DNA samples and analyses performed in connection with his/her case. A defendant may

generally have access to the forensic evidence DNA records and his/her exemplars under this provision of the DNA Act.

This provision does not authorize a defendant to access all of the DNA records in the National DNA Index. Nor does this provision authorize access to candidate matches that are not confirmed as matches and for which no personally identifiable information is released. Thus, as currently worded, the Federal DNA Act entitles a defendant to access the defendant's DNA records at NDIS as well as the forensic evidence records for the case for which the defendant is arrested, charged and/or appealing.

The FBI shall respond to requests for access to DNA records that were contributed to NDIS by a State and /or Local agency with a referral to the contributing State and/or Local agency. The FBI shall respond to a request for access to DNA records that were contributed to NDIS by the FBI, as authorized.

3.4.5 Access by Persons Whose DNA Records are at NDIS

An individual may request access to his/her DNA record for the purpose of reviewing that record and/or challenging its accuracy or appropriateness for maintenance in NDIS. An individual making a request to review his/her DNA record to the FBI Freedom of Information Office or CODIS Unit will be referred to the NDIS participating laboratory that contributed the DNA record to NDIS.

An NDIS participating laboratory is responsible for responding to requests for access to a DNA record it generated by the subject of that record once locally specified requirements are met. The FBI is responsible for responding to requests for access to FBI Laboratory—generated DNA records.

3.5 Linkage of DNA Record with Criminal History Record Information Not Permitted

In accordance with the limited access and disclosure provisions of the Federal DNA Act and the NDIS Privacy Act Notice, no personally identifiable information, including criminal history record information, shall be contained in the DNA record stored at NDIS. States may include information in the criminal history record of an offender or arrestee that a DNA sample has been collected, analyzed and/or databased to the extent permitted by their State law.

3.6 Retention and Removal of DNA Records at NDIS

In accordance with the NDIS Privacy Act Notice (see Appendix B), State or Local DNA records shall be maintained in NDIS as long as they are substantiated by the internal records of the NDIS participating laboratory and are allowed to be retained by Federal or State law, by judicial decree or by consent. The NDIS participating laboratory is responsible for maintaining a system of controls to ensure that DNA records are maintained and used in the Local DNA Index System (LDIS), the State DNA Index

System (SDIS) and NDIS in accordance with the Federal DNA Act and applicable State law, and for NDIS, in accordance with the NDIS Privacy Act Notice.

The NDIS participating laboratory is responsible for deleting State or Local DNA records if the NDIS laboratory determines that such records are no longer lawfully permitted or appropriate for retention in the system. For example, laboratories may purge DNA case files in accordance with State and Local records retention policies; in that event, the corresponding DNA record(s) must also be removed from NDIS unless there is other supporting documentation available and being retained to support the continued inclusion of that DNA record(s) in NDIS. Additionally, the NDIS participating laboratory shall have procedures that address the retention of DNA records databased and searched at the State and Local levels that are not uploaded to NDIS.

The NDIS Custodian also has the authority to determine that State or Local DNA records in NDIS shall be deleted and shall notify the affected NDIS participating laboratory of this determination and the basis for such deletion.

3.6.1 Missing Person-Related DNA Records at NDIS

DNA samples from close biological relatives can assist in the identification of a missing person. The Federal DNA Identification Act [34 U.S.C. §12592(a)(4)] authorizes the inclusion of DNA records from "analyses of DNA samples voluntarily contributed from relatives of missing persons." Accordingly, relatives of missing persons (see Table 1 for applicable specimen categories) may voluntarily contribute reference DNA samples to identify a missing person. In order for the biological relative reference DNA sample to be eligible for upload to and searching at NDIS, the biological relative shall voluntarily provide a DNA reference sample and document that voluntariness by signing a consent form in the presence of law enforcement. DNA records developed from relatives of missing person DNA samples shall only be searched against the Unidentified Human (Remains) Index (see Section 5.1 of this Manual) and not against the Forensic or Offender Indexes.

Law enforcement agencies, involved in an active missing person case (case in which a missing person report has been filed), are encouraged to collect reference DNA samples from two or more close biological relatives of such missing person (also referred to as family reference samples). For the DNA record to be searched at NDIS, law enforcement shall be involved in the collection of a DNA sample from the relative of a missing person and the law enforcement agency/representative shall document the voluntariness of the submission of such DNA sample through an appropriate consent agreement/form. The consent agreement/form documents that the DNA sample(s) was voluntarily contributed as required by the Federal DNA Act. Law enforcement shall verify the identity of the close biological relative providing the DNA sample (e.g., through presentation of an appropriate government-issued identification card).

Family reference DNA samples that are submitted by law enforcement agencies without

the appropriate documentation shall not be acceptable for upload to, and searching at, NDIS.

3.6.1.1 Removal of Relative of Missing Person DNA Record

The NDIS participating laboratory is responsible for removing the DNA record of a relative of a missing person under the following circumstances: (1) if the missing person corresponding to this reference sample has been identified; or (2) if the individual voluntarily providing the reference sample is determined not to be related to the missing person; or (3) if the individual who voluntarily provided the reference sample requests in writing that it be removed.

The DNA record of a spouse shall be removed from NDIS if the missing person corresponding to this reference sample has been identified subject to the provisions listed above.

If the missing person is identified to a set of partial remains, the relative's DNA record may remain at NDIS to facilitate identification of other remains.

3.7 Expungement

For purposes of this Chapter, expungement refers to the deletion of a DNA profile at the State and/or national index levels in response to the following: (1) for convicted offenders, a court order that has overturned a convicted offender's conviction for the qualifying offense; and (2) for arrestees, a court order documenting that the qualifying arrest charge(s) were dismissed or resulted in acquittal, or no charges were filed within the applicable time period or a requirement for removal by the laboratory when the qualifying arrest charge(s) are dismissed, resulted in acquittal, or no charges were filed within the applicable time period.

A State forensic laboratory is responsible for performing expungements; provided, however, a Local forensic laboratory may perform expungements in the event that the Local laboratory has been designated as the lead agency for the analysis and databasing of convicted offender, arrestee, detainee or other Legal Index DNA records.

3.7.1 Expunging a DNA Record

A DNA record may be expunged in response to a court order or in accordance with the requirements of Federal law as described above. Once it has been determined that a DNA record must be expunged from NDIS, the State CODIS Administrator is responsible for deleting the DNA record using the CODIS software and executing a data upload, which will result in the deletion of the DNA record from the SDIS and NDIS databases.

If a State is required by law or procedure to document that the DNA record has been properly expunged, the CODIS generated delete report shall serve as such

documentation. If the DNA record has not been deleted, the State shall contact the NDIS Custodian and request a manual deletion of the DNA record.

3.7.2 Expunging a Matched DNA Record

If a State expunges a DNA record, other than a forensic unknown, forensic mixture or forensic partial, that has generated an interstate candidate match, it is the responsibility of the State expunging the DNA record to notify any other laboratory(ies) involved in the candidate match that an expungement is being performed.

The NDIS Custodian is responsible for deleting all candidate matches associated with the DNA record from NDIS upon notification from the State.

Chapter 4.0 NDIS Acceptance Standards and Procedures

4.1 Compliance with Federal DNA Act Required for DNA Records Uploaded to NDIS

All DNA records uploaded to NDIS by NDIS participating laboratories shall be generated in accordance with the requirements of the Federal DNA Identification Act including, but not limited to, accreditation, audits, the FBI Director's *Quality Assurance Standards for DNA Databasing and Forensic DNA Testing Laboratories* (QAS) and limited access and disclosure.

Compliance with the FBI Director's QAS shall be demonstrated by completion of an external QAS audit in accordance with the Federal DNA Act that includes a review of the STR and/or sequencing ¹⁴ analysis of forensic casework, missing person-related cases and/or databasing samples. For laboratories seeking to participate in NDIS, the DNA records generated prior to the laboratory's completion of an external QAS audit shall not be eligible for upload to NDIS. If approved by the NDIS Custodian, DNA records generated by a laboratory seeking to participate in NDIS between the period of its external QAS audit and the successful completion of the NDIS Audit Review process will be eligible for upload to NDIS.

Laboratories shall comply with the QAS in effect at the time that the DNA record is generated.

4.1.1 Use of Vendor Laboratory

An NDIS participating laboratory using a vendor laboratory for the analysis of DNA samples shall ensure that it and the vendor laboratory comply with Standard 17 of the FBI's QAS.

A DNA record entered into CODIS shall be considered the exclusive property and sole responsibility of the NDIS participating laboratory that enters such record into CODIS. An NDIS participating laboratory shall be responsible for the review in accordance with QAS Standard 17 of DNA records generated by a vendor laboratory (ownership review).

¹⁴For purposes of this Manual, sequencing includes mtDNA and next generation sequencing of the required STR loci.

4.2 Standards for Acceptance of PCR DNA Records at NDIS

PCR DNA records submitted to NDIS shall be generated in accordance with Standard 9 of the QAS. All PCR DNA records offered to NDIS shall be associated with the controls and standards required by QAS Standards 9.4 (Databasing) and 9.5 (Forensic).

Only PCR DNA records generated from the analysis of NDIS Accepted PCR Kits (see Appendix E) shall be accepted at NDIS.

DNA records submitted to NDIS shall contain the required CODIS Core Loci specified in Section 4.2.2. As of January 1, 2017, the minimum number of loci required for the Offender category (includes Convicted Offender, Arrestee, Detainee, Legal and Multiallelic Offender) is the 20 CODIS Core Loci and for the Relatives of Missing Person category is the 20 CODIS Core Loci and Amelogenin. In addition, as of January 1, 2017, an analysis of all 20 CODIS Core Loci shall be attempted for Forensic samples (includes Forensic Unknown, Forensic Mixture and Forensic Partial). However, in light of the large number of DNA records already maintained at NDIS having the 13 Original CODIS Core Loci, searches will be based upon the Original CODIS Core Loci followed by the evaluation of additional loci (such as the new seven loci in the CODIS Core Loci) to effectively "filter" matches. Based upon this searching strategy, the following interpretation rules are applicable.

4.2.1 Interpretation of DNA Records

- 4.2.1.1 DNA records submitted to NDIS shall be interpretable. In accordance with the validation studies performed by and the standard operating procedures of the NDIS participating laboratory, any data used to make an exclusion can be included in the DNA record submitted to NDIS.
- 4.2.1.2 Database and reference samples shall be accurate and complete for the CODIS Core Loci; good faith efforts shall be made to obtain results for each locus and to enter all of the results as part of the DNA profile.
- 4.2.1.3 A forensic unknown, forensic mixture or forensic partial DNA record submitted to NDIS shall originate from and/or be associated with a crime scene; the source of which is attributable to a putative perpetrator. For purposes of NDIS eligibility, an item taken directly from a suspect or the suspect's possession (e.g., home, car, backpack) shall not be considered a forensic sample.

- 4.2.1.4 A forensic unknown DNA record originating from a single source (or a fully deduced profile originating from a mixture) submitted to NDIS having all 13 Original CODIS Core Loci shall not have more than 3 alleles at one locus while the remaining loci can have up to 2 alleles.
- 4.2.1.5 A forensic mixture DNA record submitted to NDIS shall not have more than 4 alleles at any locus.
- 4.2.1.6 A forensic partial DNA record originating from a single source (or a fully deduced profile originating from a mixture) with either locus or allelic dropout at any of the 13 Original CODIS Core Loci submitted to NDIS shall not have more than 3 alleles at one locus while the remaining loci can have up to 2 alleles.
- 4.2.1.7 Forensic mixture and forensic partial DNA records submitted to NDIS shall be reviewed by the submitting laboratory to ensure the DNA records have a minimum of 8 of the Original CODIS Core Loci and satisfy a statistical threshold for match rarity of one in ten million at moderate stringency (moderate match estimate).
- 4.2.1.8 A laboratory submitting a DNA record to the Forensic, Forensic Mixture, or Forensic Partial Indexes at NDIS that is derived from forensic evidence, shall only offer those alleles that are attributed to the putative perpetrator(s). Alleles derived from forensic DNA records that are unambiguously attributed to a victim or individuals other than the perpetrator(s), such as an elimination sample, shall not be offered to NDIS.
- 4.2.1.9 Composite DNA records may be submitted to NDIS.
- 4.2.1.10 DNA records developed with Enhanced Detection Methods validated in accordance with the QAS and SWGDAM Guidelines for STR Enhanced Detection Methods (available at www.swgdam.org) may be submitted to NDIS: provided, however, that only DNA records developed from unidentified human remains and other single source samples from missing person investigations or mass disasters using Low Template or Low Copy DNA Analysis validated in accordance with the QAS and SWGDAM Guidelines for STR Enhanced Detection Methods may be submitted to NDIS. No other DNA records developed using Low Template or Low Copy DNA Analysis shall be submitted to NDIS.

4.2.1.11 Forensic DNA records generated through the use of a probabilistic genotyping system validated in accordance with the QAS and SWGDAM Guidelines for the Validation of Probabilistic Genotyping Systems and interpreted by a DNA analyst pursuant to the QAS may be submitted to NDIS.

4.2.2 Required and Acceptable PCR Loci

The searching of DNA records in NDIS derived from offender (convicted offender, arrestee, detainee, multi-allelic offenders and Legal Index specimens), forensic samples (forensic, forensic mixture, forensic partial), missing person, relatives of missing person, and unidentified human remains require interpretable and conclusive results for a minimum number of required PCR loci.

The CODIS Core Loci are those loci required for upload to the National DNA Index System and consist of the following 20 loci: CSF1PO, FGA, TH01, TPOX, vWA, D3S1358, D5S818, D7S820, D8S1179, D13S317, D16S539, D18S51, D2IS11, D1S1656, D2S441, D2S1338, D10S1248, D12S391, D19S433 and D22S1045. Appendix D lists all loci required and accepted at NDIS. Loci listed in Appendix D as acceptable shall be accepted for DNA records containing the required minimum number of CODIS Core Loci. The accepted loci may be uploaded to NDIS and used in generating search results.

The addition of new PCR loci accepted at NDIS are subject to the approval of the NDIS Custodian. Additionally, any modification of the CODIS Core Loci shall be preceded by the FBI providing notice to Congress six months in advance of any such addition in accordance with Federal law [P.L. 108-405, §203(f)]. Applications for the addition of new loci to the PCR loci accepted at NDIS may be submitted to the NDIS Custodian by a NDIS participating laboratory in accordance with Appendix F.

4.2.3 Acceptable PCR Kits

The PCR Kits accepted at NDIS are listed in Appendix E.

Applications for the approval of a new or modified PCR kit shall be submitted by an NDIS participating laboratory to the NDIS Custodian in accordance with Appendix F.

4.2.4 Format for Offering PCR Profiles to NDIS

- 4.2.4.1 The DNA result from each locus will be in the form "p,q" for heterozygotes and mixtures (in ascending order) and "p,p" or "p" for homozygotes.
- 4.2.4.2 Alleles below or above the allelic ladder are entered as < (lowest

allele) or > (highest allele), respectively.

4.2.4.3 Alleles shall be entered according to their relative base pair size even if they are between designated points on the allelic ladder.

4.3 Standards for Acceptance of Mitochondrial DNA Records at NDIS

Mitochondrial (mt) DNA records submitted to NDIS shall be generated in accordance with the SWGDAM Interpretation Guidelines for Mitochondrial DNA Analysis by Forensic DNA Testing Laboratories (mtDNA Interpretation Guidelines) available at www.swgdam.org. Only DNA data relating to the mtDNA control region shall be uploaded, stored and searched at NDIS. All mtDNA records offered to NDIS shall follow the SWGDAM Nomenclature Rules described in Section 2.3.3 of the mtDNA Interpretation Guidelines.

4.4 Standards for Acceptance of Next Generation Sequencing DNA Records at NDIS

Effective May 1, 2019, next generation sequencing (NGS) DNA records submitted to NDIS shall be generated in accordance with the *Addendum to "SWGDAM Interpretation Guidelines for Autosomal STR Typing by Forensic DNA Testing Laboratories" to Address Next Generation Sequencing*, the *SWGDAM Interpretation Guidelines for Mitochondrial DNA Analysis by Forensic DNA Testing Laboratories*, and the *SWGDAM Validation Guidelines for DNA Analysis Methods* available at www.swgdam.org. All NGS DNA records offered to NDIS shall follow SWGDAM interpretation and validation guidelines referenced above.

Next generation sequencing kits produce DNA results that include the CODIS Core Short Tandem Repeat (STR) Loci, in addition to new STR loci, Y chromosomal STRs (Y STRs), X chromosomal STRs (X STRs), mtDNA, and identity Single Nucleotide Polymorphisms (SNPs). The CODIS software is not capable of storing, searching, or maintaining information on X STRs or identity SNPs¹⁵ and thus, any DNA results generated on X STRs or identity SNPs shall not be entered into NDIS. Only DNA records relating to the required CODIS Core Loci and NDIS accepted loci as specified in Appendix D shall be uploaded, stored and searched at NDIS. ¹⁶

¹⁵ While X STRs and identity SNPs cannot be stored, searched or maintained at NDIS at this time, this does not preclude the FBI from revisiting this issue in the future. This also applies to additional STR and Y STR data generated by NGS kits that is not required or accepted at NDIS at this time; this does not preclude the FBI from revisiting those loci in the future.

¹⁶ In accordance with applicable State laws and procedures, States may store and retain additional STR and Y STR loci generated by an NGS kit at SDIS and LDIS.

4.5 Standards for the Use of Expert Systems

An NDIS participating laboratory may use an Expert System approved by the FBI to generate offender and/or known reference DNA records that are eligible for upload to NDIS in accordance with the requirements of this section.

4.5.1 Definition

An Expert System is a software program or set of software programs that meets all of the following criteria:

- 1. The NDIS laboratory intends to use the system to replace one or both of the technical review processes defined in Section 12.2 of the FBI's *Quality Assurance Standards for DNA Databasing Laboratories*;¹⁷
- 2. The system performs all of the following functions without human participation ¹⁸:
 - i. Identifies peaks/bands 19
 - ii. Assigns alleles
 - iii. Ensures data meet laboratory-defined quality checks including, at a minimum, validating positive and negative controls and ladders; ensures alleles from overlapping loci are concordant (when applicable); ensures acceptable RFU values, and ensures acceptable peak height/area ratios.
 - iv. Describes the rationale behind software decisions (e.g., Why a peak wasn't considered an allele; etc.)²⁰;
- 3. The system does not make incorrect allele calls in those cases where the results are classified as "Accept" (i.e., the data can be entered directly into CODIS without manual review).²¹

4.5.2 Approval of Expert Systems for Use at NDIS

¹⁷ The NDIS laboratory is not required to comply with these requirements if the laboratory does not intend to use the Expert System to replace the manual review.

¹⁸ As soon as a human is inserted into one of these steps, all downstream steps have the potential for human participation. If human interpretation occurs while identifying peaks, then that step, and all subsequent steps, require manual review as specified in Section 12.2 of the FBI's *Quality Assurance Standards for DNA Databasing Laboratories*. For example, opening a file using a software program is generally not considered human participation unless it is opening Genotyper in non-locked mode because alleles can inadvertently be clicked on or off.

¹⁹ One of the functions of the Expert System is to flag peak(s) that contain one or more anomalies for an analyst's

review. Accordingly, the review of such a flagged peak by an analyst will only be considered human interpretation/participation if the analyst modifies the allele assignments made by the Expert System.

²⁰ It is important that each decision made by the Expert System is electronically documented.

²¹ The primary consideration for an NDIS approved Expert System is that profiles (or alleles) documented as "Accept" are always correct. Therefore, an Expert System that cannot interpret stutter (or any other data interpretation challenge) could be approved for use at NDIS, provided that profiles with stutter are never classified as "Accept". This is a subtle but important distinction. An Expert System does not have to automatically call alleles for all of the types of challenges – but it shall recognize those situations where it is incapable of making an interpretation.

Requests for approval of an Expert System used for the review of offender and/or known reference samples shall be submitted by the NDIS participating laboratory²² to the NDIS Custodian.

Developmental validation shall be conducted on all Expert Systems that have not been previously approved by NDIS. Expert Systems currently approved for use at NDIS²³ are listed below:

NDIS Approved Expert Systems
GeneMapper®ID
GeneMapper®ID-X
GeneMarker® HID
i-Cubed TM
OSIRIS ²⁴
TrueAllele TM

Internal validation shall be performed on any of the NDIS approved Expert Systems specified above in accordance with Section 4.5.4. The internally validated Expert System settings shall be submitted to the NDIS Custodian for approval prior to implementation by the NDIS participating laboratory, except that an NDIS participating laboratory using an NDIS approved Rapid DNA System (as listed in Section 4.6.2) is not required to perform an internal validation of the Expert System being used by the NDIS approved Rapid DNA System. The internal validation of an Expert System shall be specific for each of the following: software, instrument²⁵, and DNA typing kit. Please contact the NDIS Custodian for information on submission requirements.

4.5.3 Developmental Validation Criteria

Requests for the approval of an Expert System not listed in Section 4.5.2 shall be reviewed and evaluated by a panel designated by the FBI who shall consider the criteria listed below, to the extent appropriate, in determining whether to approve an Expert

²² The NDIS participating laboratory shall sponsor the approval of Expert Systems used by private laboratories (e.g., vendors that provide DNA analyses services to states under contract). In these cases it is expected that the Expert System is either: 1) proprietary to the vendor; or 2) a commercial product that is only being used by the vendor. The NDIS laboratory shall perform an ownership review as required by Standard 17 of the Quality Assurance Standards for the data generated by the vendor laboratory. That ownership review may be completed by an NDIS approved Expert System.

²³ Please refer to the CODIS and NDIS Fact Sheet at http://www.fbi.gov/about-us/lab/biometric-analysis/codis-and-ndis-fact-sheet for a current list of approved Expert Systems.

²⁴ Open Source Independent Review and Interpretation System (OSIRIS)

²⁵ For purposes of Expert System validation, instrument refers to the STR typing instrument, such as 310, 3100, 3130 or 3500. A change in the instrument model used by the laboratory, for example, replacing a 3130 instrument with a 3500 instrument, will require an internal validation in accordance with this Chapter.

System. NDIS laboratories submitting a request for approval shall address the following criteria and include supporting documentation to facilitate the review and evaluation.

- 4.5.3.1 The NDIS laboratory shall perform and complete the appropriate components of a developmental validation in accordance with Standard 8.9 of the FBI's *Quality Assurance Standards for DNA Databasing Laboratories* (Databasing QAS). The laboratory shall perform the required validation using employees of their laboratory who are not provided by or affiliated with the Expert System vendor.
 - 4.5.3.1.1 Validation shall include studies to demonstrate accuracy, precision, and reproducibility.
 - 4.5.3.1.2 The NDIS laboratory shall provide a copy of its complete validation documents with the request for data review and evaluation.
 - 4.5.3.1.3 At least 200 unique samples shall be analyzed to establish the rules and thresholds for the software (calibration set). For purposes of the submission, a "sample" shall mean a genotype resulting from the analysis of one DNA specimen from one person. The calibration set should contain a mixture of good quality and challenge samples routinely encountered in DNA analysis.
 - 4.5.3.1.4 The initial 200 unique calibration samples shall be re-run and evaluated with each trial.
 - 4.5.3.1.5 The software review procedure shall be documented.
- 4.5.3.2 A concordance study of a minimum of 1,000 unique samples shall be performed to demonstrate that the system performs as well as, or better than, the current system used by the NDIS laboratory. ^{26,27} The 200 unique calibration samples described in Section 4.5.3.1.3 shall not be included in the samples required for the concordance study; this means that a total of 1,200 unique samples shall be included in the data provided in the submission to the NDIS Custodian.
 - 4.5.3.2.1 Using data from the concordance and/or calibration study, the NDIS laboratory shall demonstrate that the Expert

²⁶ It is expected that the laboratory conducting the concordance study provides all of the samples (the concordance set) used in the study. However, in the case of outsourced DNA data, the concordance set may consist of samples submitted and approved by one or more states, provided the analytical methods and interpretation guidelines used by the vendor will be the same for all samples included in the study.

²⁷ The 1,000 samples represent the qualifying test for the Expert System.

System does not incorrectly document alleles as "Accept". The NDIS laboratory shall test the Expert System in accordance with the requirements specified by the NDIS Custodian for submission, and provide appropriate documentation.²⁸

4.5.3.2.2 The FBI reserves the right to request additional information and documentation, as necessary, in order to conduct a thorough review and evaluation.

4.5.4 Internal Validation Criteria

Laboratories that plan to use an NDIS approved Expert System shall complete an internal validation in accordance with Standard 8 of the FBI's Databasing QAS and the following criteria.²⁹

The internal or developmental validation, as applicable, shall be documented and available for review during the external QAS audit process.

The internally validated Expert System settings shall be submitted to the NDIS Custodian for approval prior to implementation by the NDIS participating laboratory. The internal validation shall be specific for each of the following: software, instrument, and DNA typing kit. Please contact the NDIS Custodian for information on submission requirements.

- 4.5.4.1 An internal validation for an approved Expert System shall also include, but may not necessarily be limited to, the following:
 - 4.5.4.1.1 At least 200 unique samples shall be analyzed to establish the rules and thresholds for the software (calibration set). The calibration set should contain a mixture of good quality and challenge samples routinely encountered in DNA analysis.
 - 4.5.4.1.2 A one-time assessment of the concordance of allele designations between the Expert System and the validated system currently in place in the laboratory for ten percent (10%) of the number of unique samples annually produced by the laboratory or 500 unique samples, whichever is

²⁸ The manual review of the data shall precede the electronic review. Subject to the prior approval of the NDIS Custodian, a review by an approved Expert System for which the laboratory has performed developmental validation may be used in place of the manual review

²⁹ A laboratory that has performed the developmental validation approved by the FBI and described in Section 4.5.3 of this Manual is not required to perform the internal validation described in this section.

less.³⁰ Samples included in this concordance test set shall be representative of samples analyzed in the laboratory (including representation of the various substrates);

4.5.4.1.3 Evaluation of non-concordant data to determine if the Expert System performs, at least as well as, the current validated allele calling procedure in the laboratory.

4.5.5 Quarterly Recertification Required for an NDIS Approved Expert System

Once an Expert System is approved for use in the review of offender and/or known reference DNA records and implemented in the NDIS participating laboratory, the laboratory shall monitor the use of the Expert System in accordance with the recertification requirements described below.

- 4.5.5.1 A recertification shall be performed by the NDIS laboratory using a defined quality control data set of a minimum of 200 unique samples. A "sample" shall mean a genotype resulting from the analysis of one DNA specimen from one person. The quality control data set may consist of sample data used in the original NDIS validation to calibrate the system with the same variety of challenging results (i.e., the calibration set) in addition to recently analyzed data. In order to be recertified for continued use, the Expert System shall demonstrate complete concordance of the defined data set with the known DNA typing results.
- 4.5.5.2 This quality control data set shall be run through an NDIS approved Expert System on a quarterly basis (regular intervals of three months). The intent of such an interval is to ensure that at least four (4) such challenges, spaced approximately three months apart, are made to the system each calendar year.
- 4.5.5.3 Documentation of the concordance results shall be retained and available for review.

4.5.6 Proficiency Test Requirements

The Expert System shall be included in the NDIS laboratory's routine, external proficiency testing program.

³⁰ This represents the qualifying test for the Expert System.

4.5.7 New Software Versions of Approved Expert Systems

New versions of an approved Expert System may be released from time to time. A major revision, such as a major functionality addition, inclusion of a new module, or modification of any algorithm, shall require internal validation in accordance with Section 4.5.4. All other version changes, such as minor software changes (new rule), minor revision changes (order of rules) and minor build changes (spelling errors, color changes, formatting) require performance of a recertification in accordance with Section 4.5.5 before implementation in the NDIS laboratory. Documentation of the recertification shall be available for review during the QAS audit process.

4.5.8 Changes to DNA Typing Kit and/or Instrument

Changes to the DNA typing kit, instrument and/or settings used with an Expert System require internal validation according to Section 4.5.4 and submission of the internal validation expert system settings to the NDIS Custodian for approval.

4.6 Rapid DNA Analysis Systems

The FBI established the Rapid DNA Program Office in 2010 to facilitate the development and integration of Rapid DNA analysis for use by law enforcement with a specific goal of integrating Rapid DNA into the booking process for the analysis of arrestee DNA samples while the arrestee is in custody. Rapid DNA analysis was first approved for use in an accredited laboratory setting where Rapid DNA analysis is used to analyze database, known or casework reference DNA samples, with or without the human intervention of a DNA analyst in the interpretation and technical review of the DNA results. The primary difference between Modified Rapid DNA analysis and Rapid DNA analysis is the integration of an Expert System within the Rapid DNA System that performs the interpretation and technical review of the DNA analysis results of the database, known or casework reference sample.

The Rapid DNA Act of 2017 (Public Law 115-50) was signed by the President on August 18, 2017. In addition to accredited forensic DNA laboratories complying with the FBI Director's Quality Assurance Standards, the Act authorizes "criminal justice agencies using Rapid DNA instruments approved by" the FBI Director in compliance with the Director's procedures and standards, to contribute DNA records to NDIS. Accordingly, law enforcement booking agencies may use NDIS approved Rapid DNA Booking Systems on buccal swabs collected from arrested individuals legally required to provide DNA samples for uploading and searching of the resulting DNA profiles at NDIS. State CODIS Agencies approved by the Federal Bureau of Investigation to operate a Rapid DNA program and their participating booking agencies shall comply with the Standards for the Operation of Rapid DNA Booking Systems by Law Enforcement Booking Agencies and the National Rapid DNA Booking Operational Procedures Manual.

These Procedures distinguish between a Rapid DNA instrument and a Rapid DNA System. The Rapid DNA instrument is the device that analyzes a DNA sample – a process that includes extraction, amplification, separation and detection. As long as in compliance with the authorized use criteria defined in Section 4.6.1, FBI approval is not required for an accredited forensic DNA laboratory to use a Rapid DNA instrument to perform Modified Rapid DNA analysis (which requires DNA analyst interpretation and technical review) on database, known or casework reference samples. A Rapid DNA instrument shall be subject to validation as required by Standard 8.0 of the *Quality Assurance Standards for DNA Databasing and Forensic DNA Testing Laboratories*.

The Rapid DNA Act of 2017 defines a Rapid DNA instrument as "instrumentation that carries out a *fully automated* process to derive a DNA analysis from a DNA sample." For the purposes of these Procedures and the applicable standards, the term "Rapid DNA System" describes the collection of components that together carry out the fully automated process of Rapid DNA analysis consisting of a Rapid DNA instrument, the PCR STR typing kit/Rapid DNA cartridge, and an integrated Expert System to develop a CODIS acceptable STR profile from a database, known or casework reference buccal sample. The procedure for approval of a Rapid DNA System and the authorized use of such system are described in Sections 4.6.2 and 4.6.3, respectively.

Only DNA record(s) generated in compliance with the following are eligible for entry in CODIS and/or searching at NDIS:

- A Rapid DNA instrument used in an accredited forensic DNA laboratory setting to perform Modified Rapid DNA Analysis on database, known or casework reference samples in accordance with the criteria specified in Section 4.6.1;
- An NDIS approved Rapid DNA System used in an accredited forensic DNA laboratory setting to perform Rapid DNA analysis on database, known or casework reference DNA buccal samples in accordance with the criteria specified in Section 4.6.3; and
- An NDIS approved Rapid DNA Booking System used in a booking agency to perform Rapid DNA analysis on a buccal sample obtained from an individual who is legally required to provide such a sample in accordance with the criteria specified in Section 4.6.3.

For purposes of uploading DNA records to CODIS and/or searching in NDIS, Rapid DNA instruments/Systems are **not** currently authorized for use on forensic (crime scene) samples.

4.6.1 Approved Use of Modified Rapid DNA Analysis in an Accredited Forensic DNA Laboratory

Setting	Accredited Forensic DNA Laboratory
Definition	The automated (hands free) process of developing a CODIS Core Loci STR profile from a database, known or casework reference sample that includes integrated extraction, amplification, separation, and detection without human intervention, but requires human interpretation and technical review.
Lead Agency	Accredited NDIS Participating Laboratory
Sample	Casework Reference Sample Biological material (e.g., buccal swab, fingerprick, or blood draw) obtained directly from a known individual and used for purposes of comparison to forensic samples.
	Database Sample
	A sample obtained from an individual who is legally required to provide a DNA sample for databasing purposes and whose identity is established at the time of collection of the sample.
	Known Sample
	Biological material whose identity or DNA type is established.
Typing Test Kit/Rapid DNA Cartridge	Any PCR STR kit accepted at NDIS in Appendix E of the NDIS Operational Procedures Manual.
	FlexPlex27 A0210001057
	GlobalFiler™ Express PCR Amplification Kit 4476609
	If using an NDIS approved PCR STR typing test kit (DNA typing kit with corresponding part number or catalogue number), the NDIS participating laboratory has documentation that the chemistries and concentrations are exactly the same as the NDIS accepted PCR STR typing kit listed in Appendix E of this NDIS Operational Procedures Manual.
	Any other Rapid DNA cartridges/chips shall be a PCR STR kit accepted at NDIS and documented in Appendix E of this <i>NDIS Operational Procedures Manual</i> .
Personnel	DNA Analyst who performs the manual interpretation and review of the data as required by <i>Quality Assurance Standards for DNA Databasing and Forensic DNA Testing Laboratories (QAS)</i> Standards 9 and 12.
Developmental	Requires full developmental validation and documentation of compliance with
Validation	Quality Assurance Standards for DNA Databasing Laboratories (Databasing QAS) Standard 8 (See Standard 8.7) and Quality Assurance Standards for

	Forensic DNA Testing Laboratories (Forensic QAS) Standard 8 (See Standard			
	8.6)			
Internal Validation	Requires full internal validation and documentation of compliance with			
	Databasing QAS Standard 8 (See Standard 8.7) and Forensic QAS Standard 8			
	(See Standard 8.6)			
Procedures	NDIS Operational Procedures Manual Section 4.6			
Standards	Databasing QAS and in particular, Standards 7.1.3.1, 8.7, 9.3.3, 9.6, 10.2.1.8			
	10.3.3.4. 10.3.4, 10.3.5, 13.1.2.1, and 13.1.5.2.			
	Forensic QAS and in particular, Standards 7.1.3.1, 8.6, 9.3.3, 9.7, 10.2.1.8,			
	10.3.3.4, 10.3.4, 10.3.5, 13.1.2.1 and 13.1.5.2.			
Accreditation	Laboratory accreditation by an approved accrediting agency (see NDIS			
	Operational Procedures Manual Section 2.1)			
Approved Use	Approved for use at NDIS only if in accordance with all criteria listed in this			
	chart.			
	Currently not approved for use with forensic (casework or crime scene) samples.			
	For purposes of uploading and/or searching CODIS, Rapid DNA instruments are			
	not currently authorized for use on forensic samples and any resulting DNA			
	records generated from the Rapid DNA analysis of forensic samples are not			
	eligible for upload to, and/or search at, any level of CODIS.			
	If planning to use a Rapid DNA instrument with a PCR STR typing kit/Rapid			
	DNA cartridge and/or Expert System, either of which were not previously			
	approved for use at NDIS, the NDIS participating laboratory shall seek approval			
	for such use in accordance with Section 4.6.2.			
	101 Such alse in accordance with Section 7.0.2.			
Compliance	If using an NDIS approved PCR STR typing test kit with the same chemistries			
*	and concentrations and all of the criteria listed in this chart are satisfied, the			
	Rapid DNA instrument does not require FBI approval to be used to perform			
	Modified Rapid DNA analysis.			
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4.6.2 Procedures for NDIS Approval of Rapid DNA Systems and Rapid DNA Booking Systems

For the purposes of these Procedures, the term "Rapid DNA System" describes the collection of components that together carry out the fully automated process of Rapid DNA analysis consisting of a Rapid DNA instrument, the PCR STR typing kit/Rapid DNA cartridge, and an integrated Expert System to develop a CODIS acceptable STR profile from a database, known or casework reference buccal sample.

4.6.2.1 NDIS Approval of a Rapid DNA System

An NDIS participating laboratory that will be submitting a request for approval for a Rapid DNA System shall contact the NDIS Custodian early in the validation process for that System³¹. Developmental validation shall be conducted on all Rapid DNA Systems where any one of the following -- PCR STR typing kit/Rapid DNA cartridge or Expert System -- is not approved for use at NDIS.

If the PCR STR typing kit/Rapid DNA cartridge used in the Rapid DNA System is not approved for use at NDIS, the validation of such Rapid DNA System shall include the criteria for validation/approval of a PCR STR typing kit as described in Appendix F of this Manual. If the Expert System used in the Rapid DNA System is not approved for use at NDIS, the validation of such Rapid DNA System shall include the criteria for validation/approval of an Expert System as described in Section 4.5 of this Manual.

An NDIS participating laboratory shall submit a written request for the approval of a Rapid DNA System to the NDIS Custodian. Requests for approval of a Rapid DNA System shall be reviewed and evaluated by a panel designated by the FBI who shall consider the criteria contained in Section 4.5 and Appendix F of this Manual, to the extent applicable and appropriate. The NDIS Custodian may request additional information and documentation, as necessary, to ensure a thorough review and evaluation.

Rapid DNA System(s) approved for use at NDIS by an accredited forensic DNA laboratory are listed below:

DNAscan 6C Rapid DNA Analysis System	DN	Ascan	6C	Rapid	DNA	Anal	vsis S	vstem
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Component	Name	Part/Version Number
Rapid DNA Instrument	ANDE 6C Instrument	A0120001003
Typing Kit	FlexPlex27	FlexPlex27
Cartridge	ANDE A-Chip (FlexPlex)	A0210001057
System Software	ANDE System Software	2.0.6
Expert System Software	ANDE Expert System	2.0.5

³¹ As an example, the developmental and internal validation for the DNAscan 6C Rapid DNA Analysis System submitted by a collaboration of 5 forensic DNA laboratories (3 of which were NDIS participating laboratories) included a total of over 2,000 buccal samples for the validation, including 1,300 unique buccal samples. All of the samples were analyzed by conventional DNA analysis methods for concordance comparison. Review of the Expert System was based upon a previous NDIS approved Expert System (2016) with the addition of two new dye colors and 11 new loci. Studies conducted by the participating laboratories were in accordance with the FBI Director's Quality Assurance Standards and SWGDAM Validation Guidelines for Forensic DNA Analysis Methods.

RapidHITTMID

Component	Name	Part/Version Number
Rapid DNA Instrument	Applied Biosystems TM RapidHIT TM ID	A41810
Typing Kit	GlobalFiler™ Express PCR Amplification Kit	4476609
Cartridge	Applied Biosystems TM RapidHIT TM ID ACE GlobalFiler TM Express	A41831
System Software	RapidHIT TM ID System Software	v1.3, v1.3.1, v1.3.2
Expert System Software	RapidHIT TM ID Expert System Software	v1.0, v1.1

An NDIS participating laboratory using an NDIS approved Rapid DNA System shall maintain documentation of developmental validation and internal validation/performance check in accordance with the *Quality Assurance Standards for DNA Databasing and Forensic DNA Testing Laboratories*.

Once a Rapid DNA System has been approved for use at NDIS by an accredited forensic DNA laboratory, there shall be no changes or modifications to the following: (1) Rapid DNA instrument; (2) the chemistries, and/or concentrations, and/or amplification parameters, of the PCR STR typing kit/Rapid DNA cartridge; (3) the settings of the Expert System; or (4) any other software parameters affecting the analysis and/or interpretation of DNA data. A manufacturer seeking to change any component of an NDIS approved Rapid DNA System shall contact the NDIS Custodian to discuss the changes and the documentation needed to submit such request to the NDIS Custodian for approval. Hotfixes/patches to approved Rapid DNA Systems and/or their components that do not affect the four criteria listed above require submission of the release notes to the FBI's CODIS Unit but shall not require an additional approval for use at NDIS. The manufacturer shall provide the release notes upon installation and such notes shall contain a description of the hotfix/patch and the levels of testing completed by the manufacturer. Installation of a software hotfix/patch is considered a service and therefore shall require a performance check in accordance with QAS Standard 10 prior to the continued use of the Rapid DNA System.

4.6.2.2 NDIS Approval of a Rapid DNA Booking System

A State CODIS Agency that will be submitting a request for approval for a Rapid DNA Booking System shall contact the NDIS Custodian early in the validation process for that System. Developmental validation shall be conducted on all Rapid DNA Booking

Systems that were not previously approved as a Rapid DNA System for accredited laboratory use.

Manufacturers of a previously approved Rapid DNA System for use in an accredited forensic DNA laboratory and seeking approval of that System as a Rapid DNA Booking System shall contact the NDIS Custodian. Appendix B of the *National Rapid DNA Booking Procedures Operational Manual* specifies the general requirements for a Rapid DNA Booking System.

A State CODIS Agency or manufacturer shall submit a written request for the approval of a Rapid DNA Booking System to the NDIS Custodian. Requests for approval of a Rapid DNA Booking System shall be reviewed and evaluated by a panel designated by the FBI who shall consider the criteria contained in Section 5 and Appendix B of the *National Rapid DNA Booking Operational Procedures Manual*, to the extent applicable and appropriate. The NDIS Custodian may request additional information and documentation, as necessary, to ensure a thorough review and evaluation.

Rapid DNA Booking System(s) approved for use at NDIS by a law enforcement booking station are listed below:

ANDE 6C Series G

RapidHITTM ID DNA Booking Systems v1.0 and v1.1

It is important to note that NDIS approval of a Rapid DNA Booking System does not include approvals demonstrating compliance with the CJIS Security Policy required by State and Local Information Technology (IT) networks. Such approvals shall be obtained before implementation of an NDIS approved Rapid DNA Booking System in a law enforcement booking agency.

Once a Rapid DNA Booking System has been approved for use at NDIS, there shall be no changes or modifications to the following: (1) Rapid DNA instrument; (2) the chemistries, and/or concentrations, and/or amplification parameters, of the PCR STR typing kit/Rapid DNA cartridge; (3) the settings of the Expert System; or (4) any other software parameters affecting the analysis and/or interpretation of DNA data. A manufacturer seeking to change any component of an NDIS approved Rapid DNA Booking System shall contact the NDIS Custodian to discuss the changes and the documentation needed to submit such request to the NDIS Custodian for approval. Hotfixes/patches to approved Rapid DNA Booking Systems and/or their components that do not affect the four criteria listed above require submission of the release notes to the FBI's CODIS Unit but shall not require an additional approval for use at NDIS. The manufacturer shall provide the release notes upon installation and such notes shall contain a description of the hotfix/patch and the levels of testing completed by the manufacturer. Installation of a software hotfix/patch is considered a service and therefore shall require a performance check in accordance with Section 3.5.2 of the Standards for

the Operation of Rapid DNA Booking Systems by Law Enforcement Booking Agencies prior to the continued use of the Rapid DNA Booking System.

4.6.3 Approved Use of Rapid DNA Systems and Rapid DNA Booking Systems (NDIS Approved)

Setting	Accredited Forensic DNA Laboratory	Law Enforcement Booking Agency
Definition	Rapid DNA System is the collection of components that together performs Rapid DNA analysis consisting of a Rapid DNA instrument, the PCR STR typing kit/Rapid DNA cartridge, and an integrated Expert System used to develop a CODIS acceptable STR profile from a database, known or casework reference buccal sample.	Rapid DNA Booking System is a fully automated system, used in a booking agency, to produce a CODIS acceptable DNA profile from an arrestee buccal swab without human interpretation in under two hours.
Lead Agency	Accredited NDIS Participating Laboratory	State CODIS Agency
Sample	A buccal swab is the only sample type currently approved for Rapid DNA Systems. Casework Reference Sample	DNA sample A buccal sample obtained from an individual who is legally required to provide a DNA sample for law enforcement databasing purposes and whose identity is
	Biological material (e.g., buccal swab) obtained directly from a known individual and used for purposes of comparison to forensic samples.	electronically verified via an electronic fingerprint capture device at the time of collection of the sample. [from Standards for the Operation of Rapid DNA Booking Systems by Law Enforcement
	Database Sample A sample obtained from an individual who is legally required to provide a DNA sample for databasing purposes and whose identity is established at the time of collection of the sample.	Booking Agencies]
	Known Sample Biological material whose identity or DNA type is established.	
Rapid DNA System	DNAscan 6C Rapid DNA Analysis System	ANDE 6C Series G
	(Please refer to Section 4.6.2.1 on page 54 for a complete listing of approved components)	RapidHIT TM ID DNA Booking Systems v1.0 and v1.1

	RapidHIT TM ID (Please refer to Section 4.6.2.1 on page 55 for a complete listing of approved components)	It is important to note that NDIS approval of a Rapid DNA Booking System does not include approvals demonstrating compliance with the CJIS Security Policy required by State and Local Information Technology (IT) networks. Such approvals shall be obtained before implementation of an NDIS approved Rapid DNA Booking System in a law enforcement booking agency.
Typing Test Kit/Rapid DNA Cartridge /Chip	Only the Rapid DNA cartridges/chips listed above for approved Rapid DNA Systems shall be used with their respective approved Rapid DNA Systems; see	Not Applicable
Personnel	Compliance section below. DNA analyst, technician and laboratory support personnel	Rapid DNA Operator Operator designated by the booking agency
	Technician is an employee or contract employee who performs analytical procedures on database, known or casework reference samples under the direction of a qualified analyst. Technicians do not interpret data to reach conclusions on typing results or prepare final documents. Laboratory support personnel (or equivalent role, position, or title as designated by the laboratory) are employees or contract employees who perform laboratory support duties exclusive of analytical procedures on database, known or casework reference	who is certified and authorized to operate a Rapid DNA Booking System in that agency. Rapid DNA Lead Operator Rapid DNA Operator designated by the booking agency who oversees the operation of a Rapid DNA Booking System(s) for their agency and is the main point of contact to the State CODIS Agency.
Developmental	samples. Documentation of compliance with	Developmental validation shall be
Validation	Quality Assurance Standards for DNA Databasing and Forensic DNA Testing Laboratories (QAS) Standard 8.2.	conducted on a Rapid DNA Booking System as described in Section 4.6.2.2.
Internal Validation	Documentation of compliance with <i>QAS</i> Standard 8.3, <i>Forensic QAS</i> 8.7 and <i>Databasing QAS</i> 8.8, as applicable (performance check).	Documentation of compliance with Standards for the Operation of Rapid DNA Booking Systems by Law Enforcement

		Booking Agencies Standard 3.5 (performance check).
Procedures	NDIS Operational Procedures Manual Section 4.6	National Rapid DNA Booking Operational Procedures Manual
Standards	Quality Assurance Standards for DNA Databasing Laboratories (Databasing QAS) and specifically, Databasing QAS Standards 7.1.3.1, 8.8, 9.3.3, 9.7, 9.7.1, 10.2.1.8, 10.3.3.4. 10.3.4, 10.3.5, 12.2, 17.1.2, and 17.3.5, 17.3.5.1, and 17.3.5.3, as applicable.	Standards for the Operation of Rapid DNA Booking Systems by Law Enforcement Booking Agencies
	Quality Assurance Standards for Forensic DNA Testing Laboratories (Forensic QAS) and specifically, Forensic QAS Standards 7.1.3.1, 8.7, 9.3.3, 9.8, 9.8.1, 10.2.1.8, 10.3.3.4. 10.3.4, 10.3.5, 12.2.2, 12.2.3, 17.3.4, 17.3.4.1, and 17.3.4.3, as applicable.	
Accreditation	Laboratory accreditation by an approved accrediting agency (see <i>NDIS Operational Procedures Manual Section 2.1</i>)	Not Applicable
Authority to Operate	Not Applicable	The State CODIS Agency shall have implemented an Arrestee DNA sample collection law that authorizes DNA sample collection from a person arrested for a specific offense at the time of arrest and, for which there are no additional requirements (i.e., determination of probable cause) for the analysis of that Arrestee DNA sample. The State shall have an Authority to Operate (ATO) from the Federal Bureau of Investigation (FBI) and a signed Memorandum of Understanding with the FBI in accordance with the <i>National Rapid DNA Booking Operational Procedures</i>
Non-DNA	Not Applicable	Manual. IT enhancements, including Live Scan and
Prerequisites		criminal history information integration, are required for a booking agency to input DNA profiles from Rapid DNA Booking Systems into CODIS for searching at NDIS as well as the following capabilities:

		The applicable booking agency shall have the capability for Electronic Fingerprint (Live Scan) integration during the booking process for the following purposes: (1) Obtaining State Identification Numbers (SID) (UCN for federal booking agencies) from the State Identification Bureau (FBI for federal) in near real time; and (2) Ensuring only qualifying Arrestees are processed to generate the Arrestee Enrollment Format (AEF) information for submission to CODIS. The applicable booking agency shall have network connectivity with the State Identification Bureau (SIB)/CJIS Systems Agency (CSA).
Approval	Section 4.6.2.1 of the NDIS Operational Procedures Manual	Section 4.6.2.2 of the NDIS Operational Procedures Manual and/or Section 5 of the National Rapid DNA Booking Operational Procedures Manual
Approved Use	Accredited laboratories performing Rapid DNA analysis on database, known or casework reference buccal samples shall only use NDIS approved Rapid DNA Systems. For purposes of uploading and/or searching CODIS, NDIS approved Rapid DNA Systems are not currently authorized for use on forensic samples and any resulting DNA records generated from the Rapid DNA analysis of forensic samples are not eligible for upload to, and/or search at, any level of CODIS.	Booking Agencies seeking to participate in a State's Rapid DNA Program shall apply to the State CODIS Agency for approval to participate. If approved, the State CODIS Agency and Booking Agency shall sign a Memorandum of Understanding (MOU) or other Agreement detailing the specific roles and responsibilities of the two parties. For purposes of uploading and/or searching CODIS, Rapid DNA Booking Systems are not authorized for use on crime scene samples.
Compliance	Once a Rapid DNA System has been approved for use at NDIS by an accredited forensic DNA laboratory, there shall be no changes or modifications to the following: (1) Rapid DNA instrument; (2) the	Once a Rapid DNA Booking System has been approved for use at NDIS, there shall be no changes or modifications to the following: (1) Rapid DNA instrument; (2) the chemistries, and/or concentrations,

chemistries, and/or concentrations, and/or amplification parameters, of the PCR STR typing kit/Rapid DNA cartridge; (3) the settings of the Expert System; or (4) any other software parameters. A manufacturer seeking to change any component of an NDIS approved Rapid DNA System shall contact the NDIS Custodian to discuss the changes and the documentation needed to submit such request to the NDIS Custodian for approval.

and/or amplification parameters, of the PCR STR typing kit/Rapid DNA cartridge; (3) the settings of the Expert System; or (4) any other software parameters. A manufacturer seeking to change any component of an NDIS approved Rapid DNA Booking System shall contact the NDIS Custodian to discuss the changes and the documentation needed to submit such request to the NDIS Custodian for approval.

Chapter 5.0 NDIS Searches

Searches at the National DNA Index System (NDIS) are performed in accordance with the following requirements of the Federal DNA Act:

- The DNA record was generated by or on behalf of a criminal justice agency. *See* 34 U.S.C. § 12592(b)(1).
- The DNA record was generated in compliance with the FBI Director's Quality Assurance Standards. See 34 U.S.C. §§ 12591(a) and 12592(b)(1).
- The DNA record was prepared by a laboratory that is accredited by a nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic science community. See 34 U.S.C. § 12592(b)(2)(A).
- The laboratory that generated the DNA record participates in annual audits and external audits every two years and maintains comprehensive records of audits and proficiency testing. See 34 U.S.C. § 12592(b)(2)(B).
- The DNA record is maintained by a Federal, State or Local criminal justice agency (or the Secretary of Defense in accordance with 10 U.S.C. §1565) pursuant to rules that allow disclosure of stored DNA samples and DNA analyses only
 - o To criminal justice agencies for law enforcement identification purposes;
 - In judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules;
 - For criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged;
 - o If personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes. *See* 34 U.S.C. § 12592(b)(3).
- The State uploading a DNA record to NDIS provides for the expungement of a DNA record of a person whose qualifying conviction has been overturned or for expungement of a DNA profile of a person arrested whose qualifying charge has been dismissed, resulted in an acquittal, or where no charge was filed within the applicable time period. See 34 U.S.C. § 12592(d)(2).

5.1 DNA Indexes Searched at NDIS

The Federal DNA Act specifies the categories of DNA records authorized to be stored, searched and maintained in NDIS (*see* Section 3.1). Accordingly, the following Indexes are searched at NDIS:

NDIS Searchable Index	idis s	earch	nable	Indexes
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Index	Forensic ³²	Offender 33	Unidentified Human (Remains)	Missing Person	Relatives of Missing Person and Pedigree Tree
Forensic ²⁴	X	X	X	X	
Offender ²⁵	X		X	X	
Missing Person	X	X	X		
Relatives of Missing Person and Pedigree Tree			X		
Unidentified Human (Remains)	X	X	X	X	X

Beginning September 1, 2020, Arrestee Rapid DNA profiles may be searched against the DNA Index of Special Concern at NDIS.

5.2 Searching at NDIS

Effective January 1, 2021, because of the substantial number of DNA records maintained at NDIS having the 13 Original CODIS Core Loci, searches will be based upon the Original CODIS Core Loci and followed by evaluation of additional available loci to effectively "filter" matches in accordance with Chapter 6.0 on *Confirmation and Hit Dispositioning*.

NDIS is searched daily on Monday through Friday to search new and modified DNA records against all records in accordance with the authorized searches described in the Table of NDIS Searchable Indexes in Section 5.1.

On at least a monthly basis, a search is run at NDIS to search new and modified missing person-related DNA records against all records in accordance with the authorized searches described in the Table of NDIS Searchable Indexes in Section 5.1.

5.3 Additional Search Capabilities³⁴

The Emergency Upload and Search Request feature of the CODIS software is now operational. This feature allows an NDIS participating laboratory to immediately search DNA records at NDIS when public safety requires such immediacy and cannot wait for

³² The reference to Forensic includes the Forensic Index, the Forensic Mixture Index and the Forensic Partial Index.

³³ The reference to Offender includes the Convicted Offender Index, the Arrestee Index, the Detainee Index, the Legal Index and the Multi-allelic Offender Index.

³⁴ Should the additional search capabilities offered by the Emergency Upload and Search Request (EUSR) functionality in the CODIS software not be available in your laboratory, please contact the NDIS Custodian.

the routine upload to and search at NDIS. Such immediate search capability is available in accordance with the following criteria: (1) the forensic DNA record to be searched is eligible for NDIS pursuant to Section 3.1.1.1 of these Procedures; (2) the forensic DNA record to be searched satisfies a statistical threshold for match rarity as described in Section 4.2.1.7 of these Procedures; and (3) the forensic DNA record to be searched was generated in accordance with Federal law as specified in Section 5.0 of these Procedures.

5.4 Search Results

Search results generated using the CODIS software will be automatically forwarded to NDIS participating laboratories involved in a match or association. The generation of search results in the form of a candidate match list does not conclude the process. The candidate match list shall be reviewed, evaluated and information released in accordance with Chapter 6.0 on *Confirmation and Hit Dispositioning*.

Chapter 6.0 Confirmation and Hit Dispositioning

NDIS participating laboratories shall follow these confirmation procedures before reporting personally identifiable information in connection with a match and report statistics to the CODIS Unit in accordance with this Chapter.

6.1 NDIS Offender Candidate Match

6.1.1 Scenario

For purposes of this Chapter, the term "offender" shall include arrestees, convicted offenders, detainees, multi-allelic offenders and Legal Index specimens authorized by the Federal DNA Act.

An Offender Candidate Match occurs when a DNA profile developed from crime scene evidence by a Casework Laboratory matches an offender's DNA profile developed by an Offender Laboratory. A Candidate Match is not a Confirmed Match and the personally identifiable information relating to a Candidate Match shall not be released unless the laboratory has confirmed the Match.

A Match Report for an Offender Candidate Match(es) produced by a search is distributed to all laboratories responsible for a DNA record included in the match. A State laboratory associated with a Local level laboratory's match also receives an electronic copy of the match.

6.1.2 Responsibilities

The following table describes the responsibilities of the laboratories involved in an Offender Candidate Match occurring at NDIS.

Responsibility	Description
Primary Responsibility	Primary responsibility includes review and
	evaluation of the match and contacting the
Casework Laboratory (having	other laboratory to coordinate match
the forensic specimen)	follow-up.
Secondary Responsibility	Secondary responsibility includes the
	following: 1) being prepared to respond to
Offender Laboratory (includes	inquiries originating from the other
Submitting Laboratory)	laboratory; and 2) making a good faith
	effort to perform its internal match
	confirmation process, review its DNA data
	and respond to the Casework Laboratory
	within 30 business days of receipt of the
	request for match follow-up.

6.1.3 Procedures

6.1.3.1 Step 1: Review the Match

The following laboratory personnel at both the Casework and Offender Laboratories review the Match to determine if the Candidate Match requires further confirmation; this typically includes considering the number of matching loci and evaluating homozygote vs. heterozygote profiles:

- A Candidate Match matching all loci at high stringency may be reviewed and evaluated by an individual who is currently or was previously a qualified DNA analyst.
- At the Casework Laboratory, a Candidate Match matching any loci at less than high stringency shall be reviewed and evaluated by a DNA casework analyst currently or previously qualified in the technology being reviewed.
 - Effective January 1, 2021, the review and evaluation of Forensic Mixture or Forensic Partial Matches based upon the Original CODIS Core Loci shall include any additional loci available in the case documentation to filter the match when determining whether to proceed to the confirmation process. This does not require the Casework Laboratory to perform additional analyses to obtain more loci for evaluation.

When the offender is excluded as a contributor to the forensic unknown, the Casework and Offender Laboratories shall disposition the Candidate Match as a no match and the confirmation process stops. Personally identifiable information relating to the offender shall not be exchanged or released, provided however, that the release of personally identifiable information in the event of a "partial match" at NDIS may be authorized in accordance with Appendix G.

6.1.3.2 Step 2: Casework Laboratory Examines Case File

At this stage, the Casework Laboratory believes the Candidate Match should be subjected to the confirmation process. The Casework Laboratory retrieves the case file and performs an administrative check to ensure the DNA record is associated with the case. Using information retrieved from the case file, the Casework Laboratory may contact the Submitting Law Enforcement Agency to determine if the case has been solved.

6.1.3.3 Step 3: Casework Laboratory Notifies Offender Laboratory

At this stage, the Casework and Offender Laboratories begin collaborating. The Casework Laboratory informs the Offender Laboratory that the Candidate Match requires confirmation. If the case is solved, the Casework Laboratory shall query the Offender Laboratory with the name associated with the solved case to determine if there are any discrepancies. If no discrepancies, the case may be dispositioned as a Conviction Match, documented, and it will not be necessary to proceed with the confirmation process. If there are discrepancies, please refer to Section 6.3 for suggested confirmation procedures.

If it is an unsolved case, both Laboratories are now aware that they are confirming a match. After being informed of the existence of a match, the Offender Laboratory initiates its internal match confirmation process. Although this process varies among laboratories, it is intended to verify that no administrative errors occurred while analyzing the offender sample. The internal match confirmation process followed by the Offender Laboratory shall include a procedure for verification of the offender's qualifying offense and the offender's identity (through the comparison of biographical data). If available, it is also recommended that the comparison of biometric data be used to confirm the offender's identity. Automation of processes (e.g., live scan or Rapid DNA) may allow streamlining of the match confirmation procedures if the offender's identity and qualifying offense are confirmed prior to the enrollment of the offender's biographical/qualifying offense data in CODIS.

If the internal match confirmation process verifies the offender's identity and offense, the match is now considered confirmed (hereinafter referred to as "confirmed match"). NDIS has produced an investigative lead in the unsolved case. If the internal match confirmation process cannot verify the offender's identity and/or offense, the Laboratory shall follow its internal procedures to determine whether or not the personally identifiable information can be released.

6.1.3.4 Step 4: Offender Laboratory Notifies Casework Laboratory

The Offender Laboratory informs the Casework Laboratory about the confirmed match and provides the personally identifiable information. Within 14 calendar days of receipt of the personally identifiable information, the Casework Laboratory shall provide notification of the confirmed match to the Submitting Law Enforcement Agency or authorized criminal justice agency. In the interests of public safety, the Offender Laboratory may also notify appropriate criminal justice agency(ies) of the confirmed match.

6.1.3.5 Confirmed Match – Follow-Up

Although notification of the confirmed match to the Submitting Law Enforcement Agency concludes the NDIS Offender Match confirmation process, it is not the end of the collaboration.

The NDIS participating laboratory shall inform the Submitting Law Enforcement Agency of the need for a legally obtained sample from the offender that documents the chain of custody. The Casework Laboratory can then perform DNA analysis on the newly obtained known biological sample submitted by the Law Enforcement Agency.

The Offender and Casework Laboratories shall disposition matches in accordance with this Chapter.

6.2 NDIS Forensic Candidate Match

6.2.1 Scenario

A Forensic Candidate Match occurs when DNA profiles developed from two or more forensic samples submitted by Casework Laboratories match one another. A Candidate Match is not a Confirmed Match and the personally identifiable information relating to a Candidate Match shall not be released unless the laboratory has confirmed the Match.

A Match Report for a Forensic Candidate Match(es) produced by a search is distributed to all laboratories responsible for a DNA record included in the match. A State laboratory associated with a Local level laboratory's match also receives an electronic copy of the match.

6.2.2 Responsibilities

The following table describes the responsibilities of the Casework Laboratories involved in a Forensic Candidate Match occurring at NDIS.

Responsibility	Description
Casework	Both Casework Laboratories are equally responsible
Laboratories	for the review and evaluation of the match and
	coordinating the match follow-up. The Casework
	Laboratory contacted for match follow-up shall make
	a good faith effort to review its DNA data and respond
	to the requesting laboratory within 30 business days of
	receipt of the request.

6.2.3 Procedures

6.2.3.1 Step 1: Review the Match

The following designated personnel at each of the Casework Laboratories review the Match to determine if the Candidate Match requires further confirmation; this typically includes considering the number of matching loci and evaluating homozygote vs. heterozygote profiles:

- A Candidate Match matching all available loci at high stringency may be reviewed and evaluated by an individual who is currently or was previously a qualified DNA analyst.
- A Candidate Match matching any loci at less than high stringency shall be reviewed and evaluated by a DNA casework analyst currently or previously qualified in the technology being reviewed.

o Effective January 1, 2021, the review and evaluation of Forensic Mixture or Forensic Partial Matches based upon the Original CODIS Core Loci shall include any additional loci available in the case documentation to filter the match when determining whether to proceed to the confirmation process. This does not require either Casework Laboratory to perform additional analyses to obtain more loci for evaluation.

If both Casework Laboratories determine that the Candidate Match is not a match, the confirmation process stops. The Casework Laboratories shall disposition the Candidate Match as a no match.

6.2.3.2 Step 2: Casework Laboratories Examine Case Files

At this stage, one or both of the Casework Laboratories believe the Candidate Match should be subjected to the confirmation process. Both of the Casework Laboratories review their respective case files and ensure the DNA records are associated with the proper cases. Using information retrieved from the case files, both Casework Laboratories may contact their respective Submitting Law Enforcement Agencies to determine if the case(s) has been solved.

6.2.3.3 Step 3: Casework Laboratories Contact Each Other and Exchange Information

The Casework Laboratories begin collaborating. One of the Casework Laboratories contacts the other Casework Laboratory to verify the match and exchange information. Both laboratories are responsible for ensuring the communication occurs.

6.2.3.4 Step 4: Casework Laboratories Document the Confirmed Match

Both Casework Laboratories have confirmed a match and they notify each other of the existence of a confirmed match and exchange information so that the Agencies can contact each other.

For a solved case matching an unsolved case, the laboratory responsible for the solved case may provide personally identifiable information; it is up to each individual jurisdiction to determine, based on applicable laws and rules, whether personally identifiable information will be disclosed.

Both Casework Laboratories document the confirmed match.

6.2.3.5 Confirmed Match – Follow-Up

Although the issuance of a laboratory notification concludes the NDIS Forensic Match confirmation process, it is not the end of the collaboration. At a minimum, both laboratories shall inform their respective Submitting Law Enforcement Agencies or authorized criminal justice agencies of the confirmed match. The Submitting Agencies can then exchange information about their respective cases.

Both laboratories shall disposition matches in accordance with this Chapter.

6.3 Confirming Identity When an Offender's Profile has Matched a Solved Case

6.3.1 Scenario

When CODIS matches a solved case with an offender, the laboratories should ensure that the putative perpetrator is the offender. The following procedure or a similar procedure developed by a participating laboratory may be used.

6.3.2 Procedures

6.3.2.1 Step 1: (Solved Case) The Names of the Offender and the Putative Perpetrator Are Compared

The initial step involves a comparison of the named offender with the name of the putative perpetrator which may be performed by the laboratory(ies) involved or the Submitting Law Enforcement Agency. If the names are different, the laboratory or Submitting Law Enforcement Agency will search the criminal history records for the offender's known aliases. If the putative perpetrator's name matches the offender's name (or aliases), the Conviction Match is confirmed. If the putative perpetrator's name does not match the offender's name (or aliases), continue on to Step 2.

6.3.2.2 Step 2: (Solved Case) Check of Identifying Information

The laboratory involved or the Submitting Law Enforcement Agency will obtain the putative perpetrator's identifying information, including fingerprints, if available, and compare that information with the information submitted with the offender's DNA sample. If the identifying information of the putative perpetrator and that of the offender match, then the putative perpetrator is using a new alias and the Conviction Match is confirmed. Notification may be provided to the appropriate authorities to update their records to include this new alias. If the identifying information of the putative perpetrator and the offender do not match, continue on to Step 3.

6.3.2.3 Step 3: (Solved Case) Internal Confirmation Procedure Implemented

If it is determined that the identifying information of the putative perpetrator does not match the identifying information of the offender, the Offender Laboratory will follow its internal match confirmation procedure to ensure that no administrative errors occurred during sample processing.

If there were no processing errors, the Offender Laboratory shall notify the Casework Laboratory that will be responsible for communicating the information to the Submitting Law Enforcement Agency or authorized criminal justice agency and that appropriate follow up is necessary.

6.4 NDIS Missing Person Procedures

6.4.1 Matches and Associations

For searches involving missing persons or unidentified human (remains), results can be defined as matches or association. When a search result involves profiles that may have originated from the same individual, the term 'match' may be used. Examples of this include unidentified human (remains) matching to an offender, or a missing person matching to a forensic unknown. Wherever possible, the confirmation of matches involving missing person or unidentified human (remains) samples should follow procedures similar to matches involving forensic samples described in Section 6.1 of this Chapter.

For searches involving the Relatives of Missing Person or Pedigree Tree Indexes, the results indicate that the unidentified human (remains) may be those of the missing person sought by the relative(s). For this reason, the term 'association' may be used. Associations are produced by using an identity search for single family references or a pedigree tree search for a ranked list of associations. Associations shall be supported by appropriate kinship statistics.

6.5 Communications

6.5.1 Follow up for Candidate Match

A laboratory may begin the confirmation process for a candidate match through a written communication with the other laboratory involved in the candidate match. It is important to include sufficient details in the written communication so that the other laboratory can respond appropriately and expeditiously. For example, for an offender candidate match, the communication should include the Match ID #, the Casework Specimen ID #, and the Offender ID #. For a forensic casework candidate match, the communication should include the Match ID #, and both Casework Specimen ID #s involved in the candidate match. Communications should identify the laboratory point of contact and his/her contact information.

6.5.2 Confirmed Offender Match

The Offender Laboratory will inform the Casework Laboratory of a confirmed offender match and provide the identity of the offender in accordance with Section 6.5.2.1. The Casework Laboratory will inform the Submitting Law Enforcement Agency of the confirmed offender match in a communication that documents the information considered in the evaluation of the confirmed offender match in accordance with Section 6.5.2.2.

6.5.2.1 Offender Laboratories

When an offender candidate match has been confirmed and personally identifiable information will be released by the Offender Laboratory, Standard 12.3 of the FBI's *Quality Assurance Standards for DNA Databasing Laboratories* requires that "the release of personally identifiable information associated with a database hit shall require an

administrative review of the official correspondence." Elements of that administrative review include:

- A review of the supporting administrative documentation and the correspondence for clerical errors, accuracy of information, and adherence to agency policy.
- A review of the individual's biographical data, qualifying offense, and DNA profile generated from reanalysis, as applicable.
- Documentation of the completion of the administrative review.

6.5.2.2 Casework Laboratories

When an offender match has been confirmed or when a forensic hit has been reviewed and deemed a match (verified), the Casework Laboratory will inform the Submitting Law Enforcement Agency of the match and the identity of the offender or the matching case(s), as applicable, in a documented communication.

For confirmed offender and verified forensic matches, any additional relevant information considered by the Casework and/or Offender Laboratories in their evaluation of the match shall be included in the communication to the Submitting Law Enforcement Agency. This may include, but is not limited to, the following:

- Type of forensic profile (mixture or partial) if using binary interpretation;
- Offender biographical information, if available, such as the age of the offender at the time of the crime or if the offender was deceased at the time of the crime;
- Offender status, if available, such as whether or not the offender was incarcerated at the time of the crime; or
- The stringency of the match.

For Casework Laboratories that utilize probabilistic genotyping software to confirm an offender match, inclusion of the forensic profile type is not necessary.

6.5.3 Confirmed Forensic Match

When a forensic candidate match has been confirmed, a Casework Laboratory with a solved case involving one of the casework specimens should include that information as well as a point of contact for the solved case.

The information considered in the evaluation of the forensic match shall be described in the communication to the Submitting Law Enforcement Agency.

6.5.4 Confirmed Missing Person Match/Association

Communications regarding missing person matches/associations should contain sufficient detail to allow the Medical Examiner or Coroner to make a fully informed decision. In these cases, the laboratory is not confirming the identity of the remains or definitively stating that a relationship exists to a reference(s). The official identification of remains,

as documented through the issuance of a death certificate, will be determined by the relevant jurisdiction based on the competent legal authority (Medical Examiner or Coroner).

The communication to the Submitting Law Enforcement Agency on the missing person match/association shall include all information considered in the evaluation of the match/association, such as metadata.

6.6 CODIS Hit Dispositioning

CODIS Administrators are responsible for the disposition of their laboratories' matches and ranks in CODIS. A laboratory shall make a good faith effort to perform its internal confirmation process, review its DNA data and respond to the other laboratory within 30 business days of receipt of the request for follow-up. If a laboratory issues a written report, the hit shall be dispositioned within 10 days of the issuance of the report. State CODIS Administrators are responsible for reconciling any disposition discrepancies.

The primary metric tracked for CODIS is the number of investigations aided; this is the number of crimes in which CODIS provided assistance, such as cases solved or serial links determined. For purposes of CODIS hit counting metrics; an investigation can only be aided once. The secondary metric that is tracked is the number of hits made by CODIS.

Missing Person-related searches include the ranking of associations between DNA profiles. Rankings are generated by CODIS as a result of a Pedigree Search comparing Unidentified Remains to Pedigree Trees. For these types of associations, as well as traditional matches involving missing person samples, Putative Identification and Identification Aided are the metrics used to track the number of times CODIS provides assistance.

6.6.1 Offender and Forensic Matches and Hits

Matches and hits are not interchangeable terms or events. A match is an association between DNA profiles. A hit is a match that is reportable to NDIS. The timing of analysis and CODIS entry may affect how hits are counted. Because it takes two samples for a hit to occur, generally the total number of hits equals the total number of samples minus one or (N-1).

A match occurs when CODIS makes an association between two or more DNA profiles and a confirmation process is started by designated laboratory personnel from each affected laboratory. A hit occurs when a confirmed or verified match aids an investigation and one or more of the case(s) involved in the match is unsolved. Agency contact may be made after the match has been detected or it may have been made immediately before the analysis of the case. If the laboratory has information that the match does not aid the investigation, a hit cannot be declared. Matching profiles may not be identical due to mixtures, primer binding site mutations, and/or allelic dropout.

6.6.1.1 Hit Counting Rules

The following rules are applicable to <u>hits</u>, not matches.

Rule #1

The level in the CODIS hierarchy (Local, State, National) at which the hit occurs gets credit for the hit.

Rule #2

An offender hit disposition takes precedence over a forensic hit disposition when the hits occur during the same search. In the event where an unsolved case profile matches a solved case previously identified as an offender hit, the hit disposition for the match will be "Offender Hit" for the hit between the forensic unsolved and the offender and all subsequent forensic unsolved to offender hits. Previous forensic hits will not be reclassified when they match an offender. Since offender hit dispositions take precedence, any new forensic to forensic matches shall be dispositioned as "Investigative Information".

Rule #3

A hit is counted for each unique set of matching profiles where at least one of the matching profiles is from an unsolved case. Because it takes two samples for a hit to occur, the total number of hits equals the total number of samples minus one or (N-1).

Rule #4

An investigation may be aided only once. Count the number of actual investigations CODIS has aided *not* the number of times CODIS has assisted a particular investigation or investigations. This reflects a direct one-to-one relationship between the metric and cases involved. As a point of clarification, an investigation with profiles from more than one source may be aided only once. Laboratories may only count their own investigations as having been aided.

Rule #5

A single hit may aid more than one investigation. A single hit may associate several separate cases. Laboratories may claim credit for all of the investigations aided within their jurisdictions.

Rule #6

An investigation aided must be associated with a hit. An investigation is aided if CODIS provides value to the investigation.

Rule #7

Only investigations of unsolved cases may be aided.

6.6.2 Missing Persons Matches and Associations

6.6.2.1 Matches and Associations

When a search result involves profiles that may have originated from the same individual, the term 'match' may be used. Examples of this include unidentified human (remains) matching to an offender, or a missing person matching to a forensic unknown. Confirmation of these types of matches results in a 'hit' even though the terminology used in counting is different.

For searches involving the Relatives of Missing Person or Pedigree Tree Indexes, the results indicate that the unidentified human (remains) may be those of the missing person sought by the relative(s). For this reason, the term 'association' is used. The rules for counting and reporting these associations are similar to the rules for matches.

It is important to note in Missing Person cases that the disposition does not mean that an identification has been made. Only the competent legal authority in each jurisdiction (such as the Medical Examiner or Coroner) can issue a death certificate confirming the identity of the unidentified human (remains).

6.7 Reporting CODIS Hit Statistics

State CODIS Administrators shall total the statistics within their jurisdiction and report the totals on a monthly basis in accordance with the schedule established by the CODIS Unit. At the State and Local level, States may continue to track the number of NDIS hits they participated in as AH_N, DH_N, FH_N, LH_N, and OH_N as described below.

The following methods will be used to minimize the duplicate counting of national hits:

- For offender hits, the Casework Laboratory will report the number of investigations aided and the Offender Laboratory will report the number of offender hits;
- For forensic hits where one case is solved, the Laboratory with the unsolved case will report the number of investigations aided and the Laboratory with the solved case will report the forensic hit; and
- For forensic hits where neither case is solved, each Laboratory will report the number of investigations aided and the Laboratory with the first entered forensic profile should report the forensic hit to NDIS.

In accordance with the rules for Offender and Forensic Matches and Hits described in Section 6.6.1, each State CODIS Administrator shall report the following data:

- AH_{S:} Arrestee hits within the State (match detected by SDIS)
- AH_{N:} Arrestee hits at NDIS (match detected by NDIS)
- DH_{S:} Detainee hits within the State (match detected by SDIS)

- DH_{N:} Detainee hits at NDIS (match detected by NDIS)
- FHs: Forensic hits within the State (sum of FH found by SDIS and LDIS labs)
- FH_N: Forensic hits at NDIS (match detected by NDIS)
- IA: Investigations Aided
- LH_S: Legal Index hits within the State (match detected by SDIS)
- LH_N: Legal Index hits at NDIS (match detected by NDIS)
- OH_S: Convicted Offender hits within the State (match detected by SDIS)
- OH_N: Convicted Offender hits at NDIS (match detected by NDIS)

Each State CODIS Administrator shall report the following Missing Person data, if applicable:

- IC_S: Confirmed Identifications within the State (sum of Identifications found by SDIS and LDIS labs)
- IC_N: Confirmed Identifications at NDIS (Identification detected by NDIS)
- ID: Identifications Aided
- PIs: Putative Identifications within the State (sum of Identifications found by SDIS and LDIS labs)
- PI_N: Putative Identifications at NDIS (Identification detected by NDIS)

APPENDIX A

Federal DNA Identification Act (excerpt) 34 U. S. C. § 12592

Section 12592. Index to facilitate law enforcement exchange of DNA identification information

- (a) Establishment of index. The Director of the Federal Bureau of Investigation may establish an index of--
- (1) DNA identification records of--
 - (A) persons convicted of crimes;
 - (B) persons who have been charged in an indictment or information with a crime; and
 - (C) other persons whose DNA samples are collected under applicable legal authorities, provided that DNA samples that are voluntarily submitted solely for elimination purposes shall not be included in the National DNA Index System;
- (2) analyses of DNA samples recovered from crime scenes;
- (3) analyses of DNA samples recovered from unidentified human remains; and
- (4) analyses of DNA samples voluntarily contributed from relatives of missing persons.
- (b) Information. The index described in subsection (a) shall include only information on DNA identification records and DNA analyses that are--
- (1) based on analyses performed by or on behalf of a criminal justice agency (or the Secretary of Defense in accordance with section 1565 of title 10) in accordance with publicly available standards that satisfy or exceed the guidelines for a quality assurance program for DNA analysis, issued by the Director of the Federal Bureau of Investigation under section 12591 of this title; (2) prepared by-
 - (A) laboratories that
 - (i) have been accredited by a nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic science community; and
 - (ii) undergo external audits, not less than once every 2 years, that demonstrate compliance with standards established by the Director of the Federal Bureau of Investigation; or
 - (B) criminal justice agencies using Rapid DNA instruments approved by the Director of the Federal Bureau of Investigation in compliance with the standards and procedures issued by the Director under section 12591(a)(5) of this title; and
- (3) maintained by Federal, State, and local criminal justice agencies (or the Secretary of Defense in accordance with section 1565 of title 10) pursuant to rules that allow disclosure of stored DNA samples and DNA analyses only--
- (A) to criminal justice agencies for law enforcement identification purposes;
- (B) in judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules;
- (C) for criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which such defendant is charged; or

- (D) if personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes.
- (c) Failure to comply. Access to the index established by this section is subject to cancellation if the quality control and privacy requirements described in subsection (b) of this section are not met.
- (d) Expungement of records.
- (1) By Director.
- (A) The Director of the Federal Bureau of Investigation shall promptly expunge from the index described in subsection (a) of this section the DNA analysis of a person included in the index—
 - (i) on the basis of conviction for a qualifying Federal offense or a qualifying District of Columbia offense (as determined under sections 40702 and 40703 of this title, respectively), if the Director receives, for each conviction of the person of a qualifying offense, a certified copy of a final court order establishing that such conviction has been overturned; or
 - (ii) on the basis of an arrest under the authority of the United States, if the Attorney General receives, for each charge against the person on the basis of which the analysis was or could have been included in the index, a certified copy of a final court order establishing that such charge has been dismissed or has resulted in an acquittal or that no charge was filed within the applicable time period.
- (B) For purposes of subparagraph (A), the term "qualifying offense" means any of the following offenses:
 - (i) A qualifying Federal offense, as determined under section 40702 of this title.
 - (ii) A qualifying District of Columbia offense, as determined under section 40703 of this title.
 - (iii) A qualifying military offense, as determined under section 1565 of title 10.
- (C) For purposes of subparagraph (A), a court order is not "final" if time remains for an appeal or application for discretionary review with respect to the order.
- (2) By States.
- (A) As a condition of access to the index described in subsection (a) of this section, a State shall promptly expunge from that index the DNA analysis of a person included in the index by that State if --
 - (i) the responsible agency or official of that State receives, for each conviction of the person of an offense on the basis of which that analysis was or could have been included in the index, a certified copy of a final court order establishing that such conviction has been overturned; or
 - (ii) the person has not been convicted of an offense on the basis of which that analysis was or could have been included in the index, and the responsible agency or official of that State receives, for each charge against the person on the basis of which the analysis was or could have been included in the index, a certified copy of a final court order establishing that such charge has been dismissed or has resulted in an acquittal or that no charge was filed within the applicable time period.
- (B) For purposes of subparagraph (A), a court order is not "final" if time remains for an appeal or

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application for discretionary review with respect to the order.	

APPENDIX B

Privacy Act Notice for the National DNA Index System July 18, 1996, Federal Register Vol. 61, No. 139

[Federal Register: July 18, 1996 (Volume 61, Number 139)]

[Notices]

[Page 37495-37498]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr18jy96-116]

DEPARTMENT OF JUSTICE [AAG/A Order No. 119-96]

Privacy Act of 1974; New System of Records

Pursuant to the provisions of the Privacy Act (5 U.S.C. 552a) and Office of Management and Budget Circular No. A-130, notice is hereby given that the Department of Justice proposes to establish a new system of records to be maintained by the Federal Bureau of Investigation.

The National DNA Index System (NDIS) (JUSTICE/FBI-017) is a new system of records for which no public notice consistent with the provisions of 5 U.S.C. 552a(e) (4) and (11) has been published in the Federal Register.

In order to comply with 5 U.S.C. 552a(e) (4) and (11), the public must be given a 30-day period in which to comment on new routine use disclosures; and the Office of Management and Budget (OMB), which has oversight responsibility under the Act, requires a 40-day period in which to review the system before it is implemented. Therefore, the public, the OMB, and the Congress are invited to submit written comments to Patricia E. Neely, Program Analyst, Information Management and Security Staff, Information Resources Management, Department of Justice, Washington, DC 20530 (Room 850, WCTR Building). Comments from the public must be received by August 19, 1996. No further notice will appear in the Federal Register unless comments are received and publication pursuant thereto is deemed appropriate. A proposed rule to exempt the system is also being published in the ''Proposed Rules"

Section of today's Federal Register.

In accordance with Privacy Act requirements, the Department of Justice has provided a report on the proposed system of records to OMB and the Congress.

Dated: July 8, 1996. Stephen R. Colgate, Assistant Attorney General for Administration. JUSTICE/FBI-017

System name:

National DNA Index System (NDIS).

System location:

Federal Bureau of Investigation: FBI Laboratory, U.S. Department of

Justice, J. Edgar Hoover Building, 935 Pennsylvania Ave., NW., Washington, DC 20535-0001.

Categories of individuals covered by the system:

Individuals in this system include persons designated by criminal justice agencies as belonging to one or more of the following groups:

- A. Convicted offenders: Persons who have been convicted of crimes in Federal, State, and/or local courts where the applicable law permits establishment of a DNA record for the convicted person.
- B. Missing persons and their close biological relatives: Persons reported missing or whose whereabouts are unknown and sought and their close biological relatives, such as parents, siblings, and children.
- C. Victims: Persons, living or dead, who have been victims of crimes where the perpetrator of the crime may have [[Page 37496]] carried DNA of the victim away from the crime scene.
- D. DNA personnel: Personnel in Federal, State, and/or local criminal justice agencies who perform duties related to or are responsible for DNA records.

Categories of records in the system:

The following definitions are used in this notice:

- A. A DNA sample is a body tissue or fluid sample usually a blood and/or buccal sample, that can be subjected to DNA analysis.
- B. A DNA profile consists of a set of DNA identification characteristics, i.e., the particular chemical form at the various DNA locations (loci), which permit the DNA of one person to be distinguishable from that of another person.
- C. A target DNA profile is a DNA profile submitted by a criminal justice agency for the purpose of identifying DNA profiles maintained by NDIS which match the target DNA profile.
- D. A target DNA profile search is a search of appropriate NDIS DNA records for those records with DNA profiles that may match the target DNA profile.
- E. Personally identifiable information is information such as names, dates of birth, or social security numbers which are normally used to identify individuals. Personally identifiable information, as used in this notice, does not include information derived from the examination of a DNA sample.
- F. A DNA record includes the DNA profile as well as data required to manage and operate NDIS, i.e., the NDIS Agency identifier which serves to identify the submitting agency; the NDIS Specimen Identification Number; information related to the reliability and maintainability of the DNA profiles; and names of the participating laboratories and DNA personnel associated with DNA profile analyses.

Records in this system do not include DNA samples but do include DNA profiles of persons described under 'Categories of Individuals Covered by the System" in paragraph A-C. DNA records are input by criminal justice agencies for use by the NDIS. NDIS includes the names of DNA personnel associated with DNA profile analyses, the date after which DNA records from a given DNA analyst can be accepted, and, when applicable, the date after which associated DNA records are not accepted. NDIS does not contain case-related or other personally identifying information about the person from whom the DNA sample was collected.

DNA records are maintained as follows:

- 1. The Convicted Offender Index, consisting of DNA records from convicted offenders;
- 2. The Missing Persons Index, consisting of DNA records from missing persons;
- 3. The Close Biological Relatives Index, consisting of DNA records from close biological relatives of missing persons;
- 4. The Unidentified Persons Index, consisting of DNA records from recovered living persons (e.g., children who can't and others who can't or refuse to identify themselves), and recovered dead persons (including their body parts and tissues), whose identities are not known;
 - 5. The Victims Index, consisting of DNA records from victims, living or dead, from whom DNA may have been

carried away by perpetrators;

- 6. The Forensic Index, consisting of DNA records from persons whose identities are not known with certainty and who left DNA at the scene of a crime or whose DNA was carried away from it; and
- 7. The Population File, consisting of DNA profiles intended to represent various population segments found in the United States. The Population File consists of DNA records from individuals whose identities may be: (a) Known to; (b) not known, but determinable under some circumstances by; or (c) not known and not determinable by the criminal justice agency submitting the DNA records to NDIS.

Authority for maintenance of the system:

The Violent Crime Control and Law Enforcement Act of 1994, Pub. L. No. 103-322, 108 Stat. 1796.

Purpose(s):

The purpose of this system and the DNA records maintained in the system is to provide a national storage medium for DNA records input by criminal justice agencies. These records can be searched in order to identify DNA associations with a DNA record obtained during an investigation of a crime or a missing person. The system is also maintained for statistical, identification research, and protocol development and quality control purposes.

In addition to DNA records, records about DNA personnel are maintained in the system. The purposes of these DNA personnel records are to control the acceptance of DNA records by NDIS and to facilitate criminal justice agency contracts required to resolve potential DNA matches.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

- 1. Direct disclosures of NDIS records are made to the Federal, State, and local criminal justice agencies who participate in NDIS. As a result of an NDIS search by a criminal justice agency, the NDIS system analyzes the target DNA profile entered by the search agency and may identify a potential match. Where NDIS identifies a potential match, the matching DNA's records will be disclosed to the criminal justice agencies associated with the match.
- 2. The Federal statute which authorizes NDIS also provides that the FBI and other criminal justice agencies participating in NDIS may make secondary or indirect disclosures of DNA records:
- (A) To criminal justice agencies for law enforcement identification purposes;
 - (B) In judicial proceedings, if otherwise admissible pursuant to applicable statutes or rules;
- (C) For criminal defense purposes, to a defendant, who shall have access to samples and analyses performed in connection with the case in which defendant is charged; or
- (D) If personally identifiable information is removed, for a population statistics database, for identification research and protocol development purposes, or for quality control purposes.

Note: Personal information such as names are not found in NDIS. However, operational identifiers such as the Specimen No., Criminal Justice Agency Identifier, and DNA Personnel identifier, are contained in NDIS. Although unlikely, the identity of an individual could, under some circumstances, be ascertained with the disclosure of such numbers for purposes stated in (D) above. This is only possible when access to a criminal justice agency's records is provided to the holder of the operational identifiers. Therefore, to ensure that such associations are not made, these operational numbers will be removed before disclosure for these purposes.

3. A record may be disclosed from this system of records to the National Archives and Records Administration and the General Services Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906, to the extent that legislation governing the records permits.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage:

[[Page 37497]]

Information maintained in NDIS is stored electronically for use in a computer environment.

Retrievability:

The primary method for retrieving information from NDIS is the target DNA profile search described in the routine use disclosure provisions of this notice.

The NDIS Custodian may retrieve records based on: the DNA profile, the NDIS Agency identifier, the NDIS Specimen Identification Number, and/or DNA personnel identifier. Criminal justice agencies with direct access to NDIS may retrieve their records by the NDIS Agency identifier, NDIS Specimen Identification Number, or DNA personnel identifier but only to inspect, modify, or delete their own DNA records.

Since NDIS records contained in NDIS do not include personal identifiers of the individuals from whom the DNA samples were collected, retrieval by personal identifiers of these record subjects is not possible.

Safeguards:

All records in NDIS are protected from unauthorized access through appropriate administrative, physical, and technical safeguards. These safeguards include restricting access to those with a need-to-know to perform their official duties, using locks and alarm devices, and encrypting data communications.

No personally identifiable information about individuals who provided DNA samples is maintained in NDIS. Therefore, names and personally identifiable information of NDIS DNA records cannot be disclosed directly from NDIS. (NDIS does, however, maintain the names of NDA personnel.)

NDIS will disclose to a criminal justice agency the DNA records of another criminal justice agency only when there is a potential DNA match. Any additional disclosures of personally identifiable information or other case-related data are made directly by the criminal justice agencies from their own files and records, not from NDIS.

Although ostensibly devoid of personally identifiable information, DNA records in NDIS contain an NDIS Specimen Identification Number, NDIS Agency identifier, and a DNA personnel identifier for law enforcement and/or general operational purposes. Since it is possible, in some circumstances, to use those numbers together with the appropriate agency's own records to identify the individuals represented by the DNA records, additional precautions are taken.

The precautions involve removal of the Specimen Identification Numbers, NDIS Agency identifiers, and DNA personnel identifiers, prior to disclosure pursuant to the 2(D) routine use. (See the ``Routine Uses of Records Maintained in the System" section of this notice.) Thus, NDIS will periodically generate DNA profile data sets, consisting of anonymous DNA profiles, for population statistics databases, for identification research and protocol development purposes, or for quality control purposes.

Criminal justice agencies are prohibited from submitting a DNA record for inclusion in the NDIS Population File for investigative purposes. The only target DNA profile searches conducted against the Population File are those necessary to eliminate duplicate DNA profiles representing the same individual.

Finally, criminal justice agencies with direct access to NDIS must agree to adhere to national quality assurance standards for DNA testing, undergo semi-annual external proficiency testing, and restrict access to DNA samples and data. The NDIS will not accept DNA analyses from those agencies and/or DNA personnel who fail to comply with these standards and restrictions; and the NDIS Custodian is authorized to restrict access to and delete any DNA records previously entered into the system.

Retention and Disposal:

DNA records generated by criminal justice agencies, together with the personal identifying information of DNA personnel, shall be retained in NDIS as long as they are substantiated by internal records of the submitting agency and are permitted either by consent, by judicial/criminal justice authority, or by Federal, State, or local law. Records may be deleted by the originating criminal justice agency or by other Federal, State, or local authorities who are responsible for deleting any records that are no longer permitted or appropriate for retention in NDIS. DNA records submitted to NDIS and then found to be inaccurate shall either be modified to achieve accuracy or deleted from NDIS by the submitting agency.

Agencies granted access to NDIS are required to establish and maintain a system of controls to ensure that continued use of their DNA records in NDIS is lawfully permitted. Such a system of controls shall ensure that DNA records in NDIS which are authorized by the consent of individuals, for example, are retained in NDIS only for the duration and within the scope of the consent.

The NDIS Custodian has the authority to determine that certain DNA records in NDIS should be deleted or, alternatively, suspended from use for a period of time determined appropriate by the NDIS Custodian. The criminal

justice agencies whose records are affected by a determination to delete or suspend records in NDIS shall be notified of this determination and the nature of the deletion or suspension. The NDIS Custodian may subsequently decide to either restore or delete the suspended records, and shall notify the affected agency of this subsequent determination.

The DNA personnel identifier for a single individual is deleted from NDIS only after all DNA records associated with that individual are deleted.

System manager(s) and address:

Director, Federal Bureau of Investigation, c/o National DNA Index System Custodian, FBI Laboratory, U.S. Department of Justice, J. Edgar Hoover Building, 935 Pennsylvania Avenue, NW., Washington, DC 20535-0001.

Notification procedure:

None. This system of records has been exempted from subsections (d) and (e)(4)(G) pursuant to subsection (j)(2) of the Privacy Act, and thus is exempt from the notification provision.

Records access procedure:

This system of records has been exempted from subsection (d) and (e)(4)(H) pursuant to subsection (j)(2) of the Privacy Act, and thus is exempt from its access provisions. NDIS does not retain information that would allow the NDIS Custodian, independent of the agency which originated the DNA record, to personally identify the record by name or other personal identifier. However, subject to applicable Federal, State, and local law and procedures, the following alternative procedures are available by which an individual may request access to records in NDIS.

- 1. Subjects of DNA Records:
- a. Convicted Offender Records: The individual may contact the Federal, State or local authority (the authorized agency) which ultimately received the collected DNA sample to obtain instructions on how to access his/her record. The authorized agency has the DNA record, if one exists, including information as to whether the DNA record has been submitted to NDIS. Only the authorized agency would have information sufficiently specific to [[Page 37498]] permit retrieval of the record from its files by name or other personally identifiable information. The authorized agency may also retrieve the DNA record, if any, that was submitted to NDIS, once locally specified requirements are met.

In addition, where a convicted offender is relocated voluntarily or involuntarily to a criminal justice agency (i.e., penal institution or parole and probation authorities) for custodial or supervisory purposes in another State or jurisdiction, the DNA record may be created by the new host criminal justice agency or other State (or Federal) authority from a DNA sample collected from the Convicted Offender at the new host criminal justice agency or other State (or Federal) authority. In such circumstances, the individual may contact such agency or authority for access instructions.

- b. Close Biological Relatives of Missing Persons and Victims; Living Victims; and Missing Persons Who Have Been Located: These individuals must contact the criminal justice agency (Federal, State, or local) which collected and processed the DNA sample to generate the DNA record. The criminal justice agency can then advise the individual about procedures for access to the DNA record. Such agency may also retrieve the DNA record, if any, that was submitted to NDIS, once locally specified requirements are met.
- 2. Records of DNA Personnel: These individuals may write to the Federal, State, or local criminal justice agency by which they are or were employed.
- 3. FBI generated records: The subject of an FBI-generated DNA record may address a Freedom of Information/Privacy Act (FOIA/PA) request to the Director, FBI, at the address given at the end of this paragraph. DNA personnel employed by the FBI may also address their requests to the system manager; however, all the information in NDIS concerning DNA personnel is also contained in the FBI's Central Records System (CRS), which may contain additional information. To request access to the CRS, DNA personnel may address an FOIA/PA request to the Director, FBI, U.S. Department of Justice, J. Edgar Hoover Building, 935 Pennsylvania Ave., NW., Washington, DC 20535-0001.

Contesting records procedure:

This system of records has been exempted from subsections (d) and (e)(4)(H) pursuant to subsection (j)(2) of the Privacy Act, and is thus exempt from its amendment and correction provisions. However, subject to applicable

Federal, State, and local laws and procedures, the following alternative procedures are available by which an individual may contest his/her records:

- 1. All Subjects of DNA Records: The requester must follow the same procedures for contesting records as those outlined under ``Record Access Procedures." In addition, the requester should be aware of the following:
- a. DNA records submitted to NDIS and contested on the basis of inaccurate information must be resolved with the criminal justice agency that submitted the DNA record NDIS. If a contested DNA record is found to be inaccurate by the criminal justice agency submitting the DNA record, such agency shall correct the inaccurate DNA record by either amending or deleting the record.
- b. DNA records submitted to NDIS and contested on the basis of the authority to retain the DNA record must be resolved with the criminal justice agency that submitted the contested DNA record. If such agency determines that the contested DNA records should not be included in NDIS, such agency must delete the contested DNA record.
- 2. Records of All DNA Personnel: DNA personnel must follow the same procedures for contesting records as those outlined under ``Record Access Procedures."

Record source categories:

DNA records in NDIS are received from Federal, State, and local criminal justice agencies. These DNA records may be derived from DNA samples obtained by Federal, State, and local and criminal justice agencies or their agents (public or private).

Systems exempted from certain provisions of the Act:

The Attorney General has exempted this system of records from subsection (c) (3) and (4); (d); (e) (1), (2), and (3); (e)(4) (G) and (H); (e) (5) and (8); and (g) of the Privacy Act pursuant to 5 U.S.C. 552a(j)(2). Rules are being promulgated in accordance with the requirements of 5 U.S.C. 553 (b), (c), and (e); and are being published in the Federal Register.

[FR Doc. 96-18328 Filed 7-17-96; 8:45 am]

APPENDIX C

FEDERAL DNA ADVISORY BOARD RESOLUTION

RESOLUTION ON REVIEW OF PRIVACY ISSUES

In accordance with the charter of the DNA Advisory Board (Board) as amended February 1, 2000, the Board has considered and discussed standards for acceptance of DNA profiles in the Federal Bureau of Investigation's (FBI's) Combined DNA Index System (CODIS) which take account of relevant privacy, law enforcement and technical issues. In the discharge of its responsibilities, the Board makes the following recommendations to the Director of the FBI:

"That the DNA Advisory Board has reviewed the access and disclosure provisions of the Federal DNA Identification Act of 1994 (42 U.S.C. §14132) and determined the provisions to sufficiently limit the scope of access to the DNA analyses and DNA samples in the national DNA identification system. Further, the Board supports the current level of enforcement of such access and disclosure provisions by the Department of Justice and the FBI and encourages the continuation of such efforts.

The Board agrees with the FBI's interpretation of the access provisions if personally identifiable information is removed, that such purposes be strictly construed to include a population statistics database, for forensic identification, forensic research and forensic protocol development purposes or for quality control purposes. These samples should only be used by the aforementioned authorities in accordance with the DNA Identification Act of 1994, should not be used for non-forensic purposes, and should not be totally consumed for research purposes because these samples should be preserved for future forensic identification.

The DNA Identification Act provides that access to the national DNA index is subject to cancellation if the privacy requirements are not met.

States receiving Federal Byrne or DNA grant funding must agree to comply with the access and disclosure provisions of the DNA Identification Act of 1994.

The Privacy Act notice for the National DNA Index System (NDIS) limits the type of data stored in NDIS and provides that no personal information concerning the convicted offender DNA specimens is stored in NDIS. The Privacy Act notice also emphasizes that the intended and primary users of NDIS are criminal justice agencies.

Additionally, the Board understands that states seeking to participate in NDIS

must execute a Memorandum of Understanding with the FBI in which they agree to comply with the access and disclosure provisions of the DNA Identification Act. A state's participation in NDIS is subject to accountability and audit. In the event that a State fails to abide by the MOU, access to NDIS will be terminated and the State will lose its license to use the CODIS software.

"That the DNA Advisory Board has reviewed state laws on access and disclosure and makes the following findings:

Forty-six states provide for the confidentiality of DNA records and/or samples.

Thirty-two states provide criminal penalties for the unauthorized disclosure of DNA records. Fifteen states penalize attempts to tamper or tampering with a DNA sample.

While half of the states appear to be more restrictive of access than the DNA Identification Act, there are several states (including those four states with no specific confidentiality provisions) that appear to permit more access than the DNA Act. Of concern are those states, who, on the face of their state laws, appear to permit more access to their DNA data and DNA samples. These states, however, have agreed to comply with the Federal DNA Identification Act, by their execution of the statutory assurances for receipt of Federal funding. Additionally, states with more permissive laws who are participating, and/or seek to participate in NDIS, must comply with the Federal DNA Identification Act and their compliance will be audited by the Department of Justice' Office of Inspector General.

Accordingly, the Board recommends that State laws on convicted offender DNA databases and databanks expressly provide for the confidentiality of DNA records and DNA samples, limit access and disclosure of the DNA records and DNA samples in accordance with the Federal DNA Identification Act of 1994 and proscribe criminal penalties for the unauthorized disclosure of DNA records and tampering with DNA samples.

"That the DNA Advisory Board endorses the recommendations of the National Commission on the Future of DNA Evidence concerning retention of CODIS convicted offender database samples and a copy of that recommendation is attached. In addition, the Board wishes to emphasize the important quality control goals facilitated by the retention of convicted offender samples."

Specifically, the Board notes that, in the event of a possible CODIS hit, the confirmation identification process may require the reanalysis of the convicted

offender DNA sample. Retention of those convicted offender DNA samples facilitates the rapid reanalysis of a convicted offender sample to confirm a possible CODIS match. Swift confirmation of a possible offender hit is important so as not to lose track of the offender (i.e., parole).

The Board is aware that currently only one state, Wisconsin, requires the destruction of the convicted offender DNA sample after analysis but that state has yet to destroy these samples because of their transition from DNA RFLP to DNA STR technology. Because new more effective DNA technologies may arise and the necessity to reanalyze the convicted offender samples for databasing may become desirable in the future, retention of these convicted offender samples is justified.

December 7, 2000 DNA Advisory Board Arlington, Virginia

Recommendation of the National Commission on the Future of DNA Evidence to the Attorney General

Retention of CODIS convicted offender database samples

On March 8, 1999, you sent the Chair of the National Commission on the Future of DNA Evidence a letter requesting that the Commission include in its deliberations and recommendations several privacy related matters including the issue of database sample retention. Pursuant to that letter, on August 31, 1999, the Commission approved its recommendations to you on the issue of arrestee sampling. Attached below is the recommendation on CODIS offender database sample retention.

Through the course of its consideration of the sample retention issue, the Commission identified both benefits to the long term retention of convicted offender samples as well as legitimate privacy questions which must be addressed, The Commission recognizes, however, that most of these issues exist because the United States remains in the early stages of DNA database use.

There are numerous arguments for and benefits to the retention of samples. First, they provide quality assurance and control. The growing trend across the country is for the expansion of the database to include more qualifying offenders in the database. The number of offenders required to be in the database continues to grow, creating more pressure on laboratories performing the analysis. A result of that trend, as well as recent recommendations by the Commission and Federal funding for the outsourcing of sample analysis, is that the number of laboratories looking to perform this work is growing. The Commission believes that, even with stringent quality control standards in place, it would be an error to deny the possibility of mistakes in the analysis of offender samples. In the event that errors are made on a large scale, the retesting of those samples could be important. Furthermore, if the need arises to retest, it is clear that re-sampling of offenders would be a very expensive process.

Many states also use retained database samples in the investigative process itself. When 'hits' are made through the database, many states confirm the validity of the hit by retesting the database samples before executing a warrant to draw a sample from the identified suspect.

Changes in DNA technology also present reasons for sample retention. Many states already face the issue of retesting old database samples as a result of the development and use of PCR technology. Those states who initially developed their databases using RFLP would be faced with the task of starting over with the offender collection process.

The Commission also recognizes that with the retention of whole blood or saliva samples from convicted offenders comes certain privacy concerns. While the nature of a digitized DNA profile at 13 STR loci used in the CODIS system present few opportunities for manipulation beyond its intended use, whole sample DNA contains significantly more sensitive information about an individual.

Recommendation:

Public trust in a DNA database system must be maintained by the continued analysis of and attention to relevant privacy considerations. Given the relatively early stage of development of the convicted offender DNA database, engendering public trust is particularly important, The issue of sample retention is one which raises many of those privacy matters and as such, should be continually evaluated.

The Commission recommends that, in no later than five years, a formal evaluation of sample retention issues should be conducted by a broad based, representative body. Sample retention, even with continued analysis of privacy issues should be conditioned on the following:

First, all states should adopt criminal penalties for the misuse of DNA records and samples. Currently, only 34 states have passed such legislation.

Second, research on database records or samples should be limited to that which is directly related to the use of DNA evidence for forensic identification purposes, unless the individuals whose DNA has been taken have given their informed consent.

APPENDIX D³⁵

PCR Loci Accepted at NDIS

PCR Loci Accepted at NDIS					
Locus	NDIS Allelic Range	Offender ¹	Forensic ²	Missing Person and Unidentified Human (Remains) ³	Relatives of Missing Person ¹
CSF1PO	<6, 6-15, >15	Required	Required	Required	Required
FGA	<18, 18-30, >30	Required	Required	Required	Required
TH01	<5, 5-10, >10	Required	Required	Required	Required
TPOX	<6, 6-13, >13	Required	Required	Required	Required
vWA	<11, 11-21, >21	Required	Required	Required	Required
D3S1358	<12, 12-19, >19	Required	Required	Required	Required
D5S818	<7, 7-16, >16	Required	Required	Required	Required
D7S820	<6, 6-14, >14	Required	Required	Required	Required
D8S1179	<8, 8-18, >18	Required	Required	Required	Required
D13S317	<8, 8-15, >15	Required	Required	Required	Required
D16S539	<5, 5-15, >15	Required	Required	Required	Required
D18S51	<9, 9-26, >26	Required	Required	Required	Required
D21S11	<24.2, 24.2-38, >38	Required	Required	Required	Required
Amelogenin	X, Y	Accepted	Accepted	Required	Required
D2S1338	<15, 15-28, >28	Required	Required	Required	Required
D19S433	<9, 9-17.2, >17.2	Required	Required	Required	Required
Penta D	<2.2, 2.2-17, >17	Accepted	Accepted	Accepted	Accepted
Penta E	<6, 6-24, >24	Accepted	Accepted	Accepted	Accepted
D1S1656	<9, 9-20.3, >20.3	Required	Required	Required	Required
D2S441	<9, 9-16, >16	Required	Required	Required	Required
D10S1248	<8, 8-18, >18	Required	Required	Required	Required
D12S391	<14, 14-27, >27	Required	Required	Required	Required
D22S1045	<8, 8-19, >19	Required	Required	Required	Required
SE33	<4.2, 4.2 - 37, >37	Accepted	Accepted	Accepted	Accepted
D6S1043	<7, 7-25, >25	Accepted	Accepted	Accepted	Accepted

The CODIS Core Loci are those listed above as 'Required'. The loci listed as 'Accepted' may be uploaded to NDIS and used in generating search results. In accordance with applicable State laws and procedures, States may store and retain additional STR loci not listed above at SDIS and LDIS.

¹The minimum number required for the Offender category (includes Convicted Offender, Arrestee, Detainee, Legal and Multi-allelic Offender) is the 20 CODIS Core Loci and for the Relatives of Missing Person category is the 20 CODIS Core Loci and Amelogenin.

³⁵ The absence of any particular locus from this Appendix does not suggest the unsuitability of the locus for forensic application.

³ An analysis of all 20 CODIS Core Loci and Amelogenin must be attempted for Missing Person and Unidentified Human (Remains).

	YSTR Loci Accepted at NDIS				
Locus	NDIS Allelic Range	Offender ¹	Forensic ²	Missing Person and Unidentified Human (Remains)	Relatives of Missing Person
DYS19	<10, 10-19, >19	Accepted	Accepted	Accepted	Accepted
DYS385	<7, 7-25, >25	Accepted	Accepted	Accepted	Accepted
DYF387S1	<30, 30-44, >44	Accepted	Accepted	Accepted	Accepted
DYS389 I	<10, 10-15, >15	Accepted	Accepted	Accepted	Accepted
DYS389 II	<24, 24-34, >34	Accepted	Accepted	Accepted	Accepted
DYS390	<18, 18-27, >27	Accepted	Accepted	Accepted	Accepted
DYS391	<8, 8-13, >13	Accepted	Accepted	Accepted	Accepted
DYS392	<7, 7-18, >18	Accepted	Accepted	Accepted	Accepted
DYS393	<8, 8-16, >16	Accepted	Accepted	Accepted	Accepted
DYS438	<8, 8-12, >12	Accepted	Accepted	Accepted	Accepted
DYS437	<13, 13-17, >17	Accepted	Accepted	Accepted	Accepted
DYS439	<8, 8-15, >15	Accepted	Accepted	Accepted	Accepted
DYS448	<17, 17-24, >24	Accepted	Accepted	Accepted	Accepted
DYS449	<22, 22-40, >40	Accepted	Accepted	Accepted	Accepted
DYS456	<13, 13-18, >18	Accepted	Accepted	Accepted	Accepted
DYS458	<14, 14-20, >20	Accepted	Accepted	Accepted	Accepted
DYS460	<7, 7-14, >14	Accepted	Accepted	Accepted	Accepted
DYS481	<17, 17-32, >32	Accepted	Accepted	Accepted	Accepted
DYS518	<32, 32-49, >49	Accepted	Accepted	Accepted	Accepted
DYS533	<7, 7-17, >17	Accepted	Accepted	Accepted	Accepted
DYS549	<7, 7-17, >17	Accepted	Accepted	Accepted	Accepted
DYS570	<10, 10-25, >25	Accepted	Accepted	Accepted	Accepted
DYS576	<11, 11-23, >23	Accepted	Accepted	Accepted	Accepted
DYS627	<11, 11-27, >27	Accepted	Accepted	Accepted	Accepted
DYS635	<20, 20-26, >26	Accepted	Accepted	Accepted	Accepted
DYS643	<6, 6-17, >17	Accepted	Accepted	Accepted	Accepted
YGATAH4	<8, 8-13, >13	Accepted	Accepted	Accepted	Accepted
Y-Indel	1,2	Accepted	Accepted	Accepted	Accepted

²An analysis of all CODIS Core Loci must be attempted for the Forensic category (includes Forensic Unknown, Forensic Mixture and Forensic Partial). A minimum of the 13 Original CODIS Core Loci is required to routinely search a Forensic Unknown profile, provided however, that a minimum of 8 of the Original CODIS Core Loci is required to routinely search a Forensic Mixture or Forensic Partial profile if such profile satisfies a statistical threshold for match rarity of one in ten million at moderate stringency (moderate match estimate).

In accordance with applicable State laws and procedures, States may store and retain additional Y STR loci not listed above at SDIS and LDIS.

MtDNA Data Accepted at NDIS					
Regions	Searchable Positions	Offender ¹	Forensic ²	Missing Person & Unidentified Human (Remains)	Relatives of Missing Person
HV1	(16,024- 16,365)*	Accepted	Accepted	Accepted	Accepted
HV2	73-340*	Accepted	Accepted	Accepted	Accepted
Control Region	16024-576	Accepted	Accepted	Accepted	Accepted

^{*}For Forensic DNA records, a minimum of 600 bases in the defined regions of HV1 and HV2, is required.

¹The Offender category includes Convicted Offender, Arrestee, Detainee, Legal and Multi-allelic Offender.

²The Forensic category includes Forensic Unknown, Forensic Mixture and Forensic Partial.

¹The Offender category includes Convicted Offender, Arrestee, Detainee, Legal and Multi-allelic Offender.

²The Forensic category includes Forensic Unknown, Forensic Mixture and Forensic Partial.

APPENDIX E³⁶

PCR STR Kits Accepted at NDIS³⁷

PCR STR Kits Accepted at NDIS		
Manufacturer	Kit Name	
ANDE	FlexPlex27 (A0210001057)	
Life Technologies (AB)	AmpF/STR® Profiler Plus® (Part Number 4303326)	
Life Technologies (AB)	AmpF/STR® COfiler® (Part Number 4305246)	
Life Technologies (AB)	AmpF/STR® Profiler Plus® and AmpF/STR® COfiler® (Part Number 4305979)	
Life Technologies (AB)	AmpF/STR® Profiler Plus® ID (Part Number 4330284)	
Life Technologies (AB)	AmpF/STR® Profiler Plus® ID and AmpF/STR® COfiler® (Part Number 4330621)	
Life Technologies (AB)	AmpF/STR® Identifiler® (Part Number 4322288)	
Life Technologies (AB)	AmpF/STR® Identifiler®Direct (Part Number 4408580)	
Life Technologies (AB)	AmpF/STR® Identifiler®Plus (Part Number 4427368)	
Life Technologies (AB)	GlobalFiler® Express (Part Numbers 4474665 & 4476609)**	
Life Technologies (AB)	GlobalFiler® (Part Number 4476135)**	
Thermo Fisher Scientific	VeriFiler Express [™] (Catalog Numbers A32014, A32070, A33032)	
Thermo Fisher Scientific	VeriFiler Plus™ (Catalog Number A35495)	
Promega	PowerPlex® 1.1(Catalog numbers DC6091/6090)	
Promega	PowerPlex® 1.2 (Catalog numbers DC 6101/6100)	
Promega	PowerPlex® 2.1 (Catalog numbers DC 6471/6470)	
Promega	PowerPlex® 16 (Catalog numbers DC 6531/6530)	
Promega	PowerPlex® 16 BIO (Catalog numbers DC 6541/6540)	
Promega	PowerPlex® 16 HS (Catalog numbers DC 2100/2101)	
Promega	PowerPlex® 18 D (Catalog numbers DC 1802/1808)	
Promega Promega	Powerplex® Fusion (Catalog numbers DC 2402/2408)** Powerplex® Fusion 6C (Catalog numbers DC 2705/2720/2780)**	
Promega Monoplex*	Monoplex D5S818 (Catalog number DC6161)	
Promega Monoplex*	Monoplex D7S820 (Catalog number DC6141)	
Promega Monoplex*	Monoplex D13S317 (Catalog number DC6151)	
Promega Monoplex*	Monoplex D16S539 (Catalog number DC6131)	
Promega Monoplex*	Monoplex TH01 (Catalog number DC5081)	
Promega Monoplex*	Monoplex TPOX (Catalog number DC5111)	
Promega Monoplex*	Monoplex CSF1PO (Catalog number DC5091)	

³⁶ The absence of a PCR, miniSTR or YSTR Kit from this Appendix does not suggest the unsuitability of that particular PCR Kit for forensic application.
³⁷ PCR kits in **bold** contain the required 20 CODIS Core Loci required effective January 1, 2017.

Promega Monoplex*	Monoplex vWA (Catalog number DC5141)
Qiagen	Investigator 24plex QS (Catalog numbers 382415/382417)**
Qiagen	Investigator 24plex GO! (Catalog numbers 382426/382428)**

^{*}Monoplexes are all fluorescene-labeled and have same chemistry as when contained in multiplex kits.

PCR miniSTR Kits Accepted at NDIS

PCR miniSTR Kits Accepted at NDIS*		
Manufacturer	Kit Name	
Life Technologies (AB)	AmpF/STR™ MiniFiler™ (Part Number 4373872)	

^{*}Because kits containing miniSTR loci are designed to address compromised DNA samples, a laboratory planning to use a miniSTR kit to generate DNA records for upload to NDIS shall review and re-evaluate existing analytical thresholds, stochastic thresholds and interpretation guidelines, as appropriate, during its validation and implementation of the miniSTR kit.

YSTR Kits Accepted at NDIS

YSTR Kits Accepted at NDIS*		
Manufacturer	Kit Name	
Life Technologies (AB)	AmpFlSTR TM Yfiler TM (Catalog number 4359513)	
Life Technologies (AB)	AmpFlSTR™Yfiler™ Plus (Catalog numbers 4484678/4482730)	
Promega	Powerplex® Y (Catalog numbers 6760/6761)	
Promega	Powerplex® Y23 (Catalog numbers DC2305/DC2320)	

^{*}Because YSTR multiplex kits can exhibit elevated stutter, a laboratory planning to use a YSTR multiplex kit to generate DNA records for upload to NDIS shall review and re-evaluate existing analytical thresholds, stochastic thresholds and interpretation guidelines, as appropriate, during its validation and implementation of the YSTR multiplex kit.

NGS Kits Accepted at NDIS

NGS Kits Accepted at NDIS			
Manufacturer	Kit Name	<u>Technology</u>	
Promega	PowerSeq [™] CRM Nested System (Catalog # AX5810)	MtDNA	
Thermo Fisher Scientific	Applied Biosystems™ Precision ID mtDNA Whole Genome Panel (Catalog # A30938)**	MtDNA***	
Verogen	ForenSeq [™] DNA Signature Prep Kit (TG-450-1001/TG-450-1002)*	STR, YSTR	

^{**}For these megaplex STR kits, it is important for laboratories to review and re-evaluate existing analytical thresholds, stochastic thresholds and interpretation guidelines, as appropriate, during validation and implementation of these kits.

*A laboratory shall determine if evaluation of locus specific analytical and stochastic thresholds are necessary as part of its validation of the kit in accordance with manufacturer recommendations. For example, for the ForenSeqTM DNA Signature Prep Kit, the manufacturer recommends using caution for interpretation of DYS392 and D22S1045 (see https://verogen.com/wp-content/uploads/2018/08/ForenSeq-DNA-Prep-Guide-VD2018005-A.pdf at pages 32, 35, and 38-40).

**A laboratory must evaluate homopolymeric regions as part of its validation. Laboratories planning to use the Applied BiosystemsTM Precision ID mtDNA Whole Genome Panel in conjunction with the applicable instrumentation must exercise care in developing interpretation parameters for the homopolymeric regions.

*** Only mtDNA control region data is approved for upload to NDIS.

APPENDIX F

Guidelines for Submitting Requests for Approval of New PCR Loci or New/Modified PCR Kits

F.1 Establishment of CODIS Core Loci

The Federal Bureau of Investigation (FBI) is responsible for specifying the CODIS Core Loci and required controls for submission of DNA records to NDIS.

The FBI, in consultation and collaboration with the forensic science community, established core loci for PCR DNA records for inclusion in NDIS (also known as "CODIS Core Loci"). For the PCR data, the FBI has also approved PCR kits for use at NDIS.

The FBI encourages the NDIS participating laboratories to continue in these collaborations and when appropriate, submit requests for the approval of new loci and/or new PCR kits.

F.2 Request for Approval of New PCR Loci or New/Modified PCR Kits

A request to add a new locus or a new PCR kit shall be submitted by an NDIS participating laboratory to the NDIS Custodian and include the appropriate documentation.

The NDIS Custodian shall be contacted for any changes or modifications to a PCR kit previously approved for use at NDIS.

F.3 Criteria Used in Reviewing Requests

Requests submitted to the NDIS Custodian for the approval of new loci or a new/modified PCR kit will be reviewed and evaluated by a panel designated by the FBI. The panel will consider the following criteria, as appropriate, in determining whether to approve a new locus or a new PCR kit for a specific application:

- 1. Concordant Studies (including performance and validation studies for different platforms)
- 2. Mixed Samples
- 3. Non-Probative Samples
- 4. Population Studies
- 5. Precision Studies
- 6. Proficiency/Qualifying Samples
- 7. Reproducibility
- 8. Sensitivity Assays (to determine the best template for successful amplification)

9. Articles, if any, submitted for publication relating to the internal validation studies 10. And such other information as may be needed by the FBI in order to make a determination on the compatibility and suitability of the loci or kit for use at NDIS

The NDIS participating laboratory submitting a request shall address the criteria referenced above and include appropriate documentation. The documentation relating to the studies referenced above should include the number of samples or cases analyzed and a summary of the study and results.

The FBI reserves the right to request additional information and documentation, as necessary, in order to conduct a thorough review and evaluation.

F.4 Response to Request

Once a determination is made by the FBI panel and approved by the NDIS Procedures Board, the NDIS participating laboratory shall be contacted with the response to the request.

Any modification of the CODIS Core Loci shall be preceded by the FBI providing notice to Congress six months in advance of any such addition in accordance with Federal law [34 U.S.C. §40721].

NDIS acceptable PCR loci and kits are listed in Appendices D and E, respectively.

APPENDIX G

Plan for the Release of Information in the Event of a "Partial Match" at NDIS

For purposes of this Plan, a "partial match" is a moderate stringency candidate match between two single source profiles having at each locus at least one allele in common indicating that a potential familial relationship may exist between the offender and the putative perpetrator (casework) profiles. A partial match when seen at NDIS is a fortuitous event. A "partial match" is not an exact match of two profiles as customarily used to infer the identity of the perpetrator.

The CODIS Unit is aware that there may be certain circumstances when NDIS participating laboratories encounter a candidate match that could be classified as a "partial match." For those candidate matches occurring at NDIS, the FBI has developed procedures with accompanying guidance to allow for the disclosure of personally identifiable information by NDIS participating laboratories in appropriate cases.

The FBI is implementing this Plan to provide guidance to Casework Laboratories to pursue partial matches identified at NDIS in accordance with applicable State law and policies. This guidance will also assist the Offender Laboratory determine whether to disclose information in accordance with applicable State law and policies to the Casework Laboratory requesting identifiable information. Forensic Partial and Forensic Mixture profiles shall not be considered for purposes of determining a partial match.

The Plan for the release of information to an NDIS participating laboratory is as follows:

1. Casework Laboratory

- a. A Casework Laboratory involved in a partial match, after documented consultation with its agency's legal representative and the relevant prosecutor, may send a written request for the release of the personally identifiable information of the offender involved in the partial match to the Offender Laboratory.
- b. The Casework Laboratory shall direct a written request for the release of personally identifiable information of the offender involved in the partial match, on the agency letterhead, to the Offender Laboratory and shall include the documented concurrence of the prosecutor. The Casework Laboratory shall provide the NDIS Custodian with a copy of the correspondence to the Offender Laboratory.
- c. The casework profile must be a single source forensic unknown profile with a minimum of the 13 Original CODIS Core Loci.
- d. The written request by the Casework Laboratory shall include the statistical

analysis used to conclude that there may be a potential familial relationship between the profiles identified by the Casework Laboratory and the Offender Laboratory.

- e. Individual Expected Match Ratios (EMR) and Expected Kinship Ratios (EKR) shall be calculated according to "SWGDAM recommendations to the FBI Director in the "Interim Plan for the Release of Information in the Event of a 'Partial Match' at NDIS." The Casework Laboratory shall not submit a request to the Offender Laboratory that does not satisfy the EKR and EMR thresholds recommended by SWGDAM.
- f. The Casework Laboratory shall notify the NDIS Custodian in writing of the outcome of any further investigation and the final resolution of any resulting prosecution in the criminal case no later than 30 calendar days from the Casework Laboratory's notification by the prosecutor, other law enforcement entity or other reliable source of that outcome and resolution. The NDIS Custodian should be notified as to whether the criminal case was solved using the partial match information.

2. Offender Laboratory

- a. The Offender Laboratory shall be responsible for determining whether the release of the offender's personally identifiable information is prohibited by its applicable State law or policies.
- b. The Offender Laboratory may request the Casework Laboratory perform additional DNA analysis (such as Y-STR and mtDNA), if appropriate to provide additional genetic data in common between the partial match offender and the putative perpetrator.
- c. If the Offender Laboratory determines that the release of the offender's identity is permitted by its applicable State law or policies, the Offender Laboratory shall provide written notification of that determination and the offender's identity, on agency letterhead, to the Casework Laboratory. The Offender Laboratory shall provide the NDIS Custodian with a copy of the correspondence to the Casework Laboratory with the offender's personally identifiable information redacted.
- d. If the Offender Laboratory determines that the release of the offender's identification is not permitted by its applicable State law or policies, the Offender Laboratory shall provide written notification of that determination, on agency letterhead, to the Casework Laboratory. The Offender Laboratory shall provide the NDIS Custodian with a copy of the correspondence to the Casework Laboratory.
- e. The determination of the Offender Laboratory having responsibility for the

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offender information shall be final.	

GLOSSARY

Accreditation

Formal recognition that a DNA laboratory is competent and meets or exceeds a list of standards, including the FBI Director's Quality Assurance Standards, to perform specific tests by a nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic science community in accordance with the provisions of the Federal DNA Identification Act (34 U.S.C. §12592) or subsequent laws.

Accrediting Agencies

A nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic science community in accordance with the provisions of the Justice for All Act of 2004 (codified at 34 U.S.C.§12592(b)(2)).

Applicable Legal Authorities

A state law authorizing the collection of a DNA sample from a defined group of persons.

Arrestee (Specimen Category)

The known sample from a person who has been arrested and in accordance with the law of the applicable jurisdiction is required to provide a DNA sample for analysis and entry into a state DNA database. The term "arrestee" includes persons who have been charged in a formal criminal instrument, such as an indictment or an information. The DNA record for this specimen category is stored in the Arrestee Index.

Arrestee Index

An Arrestee Index consists of DNA records of persons who have been arrested or indicted or charged in an information with a crime and are required by law to provide DNA samples.

Association

A search result that pairs unidentified human (remains) with one or more reference samples or Pedigree Trees; it does not reflect a direct identity match between profiles.

Biological Child (Specimen Category)

The known reference sample voluntarily provided by an adult child or provided with the parental/guardian consent for a minor child of a reported missing person. The DNA record for this specimen category is stored in the Relatives of Missing Person Index and the Pedigree Tree Index.

Biological Father (Specimen Category)

The known reference sample voluntarily provided by the biological father of a reported missing person. The DNA record for this specimen category is stored in the Relatives of Missing Person Index and the Pedigree Tree Index.

Biological Mother (Specimen Category)

The known reference sample voluntarily provided by the biological mother of a reported missing person. The DNA record for this specimen category is stored in the Relatives of Missing Person Index and the Pedigree Tree Index.

Biological Sibling (Specimen Category)

The known reference sample voluntarily provided by the full or half biological adult sibling or provided with the parental/guardian consent of a full or half biological minor sibling of a reported missing person. The DNA record for this specimen category is stored in the Relatives of Missing Person Index and the Pedigree Tree Index.

Candidate Match

A possible match between two or more DNA profiles discovered by CODIS software.

Casework CODIS Administrator

An employee of the laboratory responsible for administration and security of the laboratory's CODIS at a laboratory performing DNA analysis on forensic and casework reference samples. All references to "CODIS Administrator" in the NDIS Operational Procedure Manual are applicable to the casework CODIS Administrator referenced in the FBI *Quality Assurance Standards for Forensic DNA Testing Laboratories*, unless otherwise noted.

Casework Laboratory

The laboratory responsible to NDIS for a DNA profile developed from crime scene evidence and/or unidentified human (remains). A casework laboratory routinely develops profiles from casework related known standards: suspect, victim, and elimination and may develop profiles from other types of samples, e.g., arrestees and samples associated with missing persons.

Casework Reference Sample

Biological material (e.g., buccal swab) obtained directly from a known individual and used for purposes of comparison to forensic samples.

CODIS Administrator

An employee of the laboratory and CODIS user who is responsible for administration and security of the laboratory's CODIS at a laboratory performing DNA analysis on forensic and casework reference samples or a laboratory that owns the database and/or known samples.

CODIS Contract User

An employee of a vendor laboratory who meets the requirements of a qualified DNA analyst and is responsible for producing DNA profiles stored in NDIS but is not authorized to read, add, modify or delete DNA records in CODIS. A CODIS Contract user does not

fulfill the NDIS requirements for DNA data review and acceptance.

CODIS Core Loci

The loci specified by the Federal Bureau of Investigation for PCR DNA records that are required for inclusion in the National DNA Index System. Effective January 1, 2017, the CODIS Core Loci required for inclusion in the National DNA Index System are: CSF1PO, FGA, TH01, TPOX, vWA, D3S1358, D5S818, D7S820, D8S1179, D13S317, D16S539, D18S51, D2IS11, D1S1656, D2S441, D2S1338, D10S1248, D12S391, D19S433 and D22S1045. See also Original CODIS Core Loci.

CODIS IT User

A government employee of the NDIS participating laboratory or an IT contractor working on-site at the NDIS participating laboratory or its supervisory criminal justice agency, who has login access to the CODIS (i.e., State or Local) system for computer hardware/software and telecommunications maintenance purposes and who shall be processed as a CODIS IT user (and not as a CODIS Contract user). CODIS IT users are not authorized to add, modify or delete DNA records in CODIS.

CODIS SEN/WAN User

A designated government employee of the NDIS participating laboratory who has access to the CODIS Shared Enterprise Network (SEN)/Wide Area Network (WAN) to perform his/her job but who is not authorized to add, modify or delete DNA records in CODIS.

CODIS User

A government employee who: (1) has login access to the CODIS (i.e., State or Local) system and is authorized to read, add, modify or delete DNA records in CODIS; or (2) is a qualified DNA analyst responsible for producing DNA profiles stored in NDIS.

Composite

A DNA profile generated by combining typing results from different loci obtained from multiple injections of the same amplified evidentiary sample and/or multiple amplifications of the same DNA extract from an evidentiary sample. When separate extracts from a given item are combined prior to amplification, the resulting DNA profile is not considered a composite profile. Unless there is a reasonable expectation of sample(s) originating from a common source (e.g., duplicate vaginal swabs, known reference samples, or a bone), allelic data from separate extractions from different locations on a given evidentiary item should not be combined into a composite profile. The laboratory should establish guidelines for determining the suitability of developing composite profiles from such samples.

Contract Employee

An individual that provides DNA typing and/or analytical support services to the NDIS participating laboratory. The person performing these services must meet the relevant qualifications for the equivalent position in the NDIS participating laboratory. A contract employee cannot serve as a casework CODIS Administrator, CODIS Administrator, or

technical leader and cannot be counted as a full-time qualified DNA analyst for purposes of satisfying the definition of a laboratory. Employment of a contract employee by multiple NDIS participating and/or vendor laboratories shall be disclosed and shall only be permitted subject to approval by the technical leader of the NDIS participating laboratory for which the contract employee is performing DNA typing and/or analytical services. A contract employee working as a qualified DNA analyst for an NDIS laboratory shall be processed as a CODIS user (and not a CODIS Contract user).

Convicted Offender (Specimen Category)

The known sample from a person who has been convicted of a Federal, Military or State qualifying offense in a jurisdiction that requires that persons convicted of enumerated crimes or qualifying offenses provide a DNA sample for analysis and entry into a Federal, Military or State DNA database. The DNA record for this specimen category is stored in the Convicted Offender Index.

Convicted Offender Index

A Convicted Offender Index consists of DNA records from offenders convicted of qualifying State crimes and juveniles required by the relevant jurisdiction to provide DNA samples.

Conviction Match

A forensic DNA profile is matched by CODIS to a DNA profile from an offender (Convicted Offender Index, Arrestee Index, Detainee Index, Legal Index), but the crime from which the evidence was collected has already been solved and the match does not aid the investigation in any way.

Criminal Justice Agency

A criminal justice agency is an agency or institution of the Federal, State, or Local government, other than the office of the public defender, which performs as part of its principal function, activities relating to the apprehension, investigation, prosecution, adjudication, incarceration, supervision or rehabilitation of criminal offenders.

Database Sample

A sample obtained from an individual who is legally required to provide a DNA sample for databasing purposes and whose identity is established at the time of collection of the sample.

Deduced Missing Person (Specimen Category)

The DNA profile of a reported missing person that has been generated by examining intimate items purported to belong to the missing person such as a toothbrush, and compared to close biological relatives, if possible. Considered a reference sample, this DNA record is stored in the Missing Person Index.

Designated State Official

The person designated by a participating State to make decisions and to contract on behalf of the State.

Detainee (Specimen Category)

The known sample from a non-United States (U.S.) person detained under the authority of the U.S. and required by law to provide a DNA sample for analysis and entry into a State/national DNA database. The DNA record for this specimen category is stored in the Detainee Index.

Detainee Index

A Detainee Index consists of DNA records from non-United States (U.S.) persons detained under the authority of the U.S. and required by law to provide a DNA sample.

DNA Analyst

An employee that has successfully completed the laboratory's training requirements for casework, database, known or casework reference sample analysis, passed a competency test, and had entered into a proficiency testing program in accordance with the FBI's *Quality Assurance Standards for Forensic DNA Testing or DNA Databasing Laboratories*. This individual conducts and/or directs the analysis of samples, interprets data and reaches conclusions.

DNA Index of Special Concern

A DNA Index of Special Concern consists of forensic unknown DNA records designated by the NDIS participating laboratory and developed from unsolved homicide, rape/sexual assault, kidnapping and terrorism cases, which will be searched against rapidly enrolled arrestee DNA records.

DNA Profile

The genetic constitution of an individual at defined locations (also known as loci) in the DNA. A DNA profile derived from nuclear DNA typically consists of one or two alleles at several loci (e.g., short tandem repeat loci). The DNA profile derived from mitochondrial DNA is described in relation to the revised Cambridge Reference Sequence (Nature Genetics 1999, 23:147).

DNA Record

A database record that includes the DNA profile as well as data required to manage and operate NDIS, i.e., the Originating Agency Identifier which serves to identify the submitting agency; the Specimen Identification Number; and DNA personnel associated with the DNA profile analyses.

DNA Sample

A DNA sample means a tissue, fluid, or other bodily sample of an individual on which a DNA analysis can be carried out.

Elimination (Specimen Category)

A specimen category in the CODIS software that is voluntarily contributed by an individual for purposes of eliminating their alleles from a Forensic Sample and consideration as the putative perpetrator(s). An elimination sample includes a DNA sample voluntarily contributed by the victim(s) of the crime.

Employee

A person: (1) in the service of the applicable Federal, State or Local government, subject to the terms, conditions and rules of Federal, State or Local employment and eligible for the Federal, State or Local benefits of service; or (2) formerly in the service of a Federal, State or Local government who returns to service in the agency on a part-time or temporary basis. For purposes of a vendor laboratory, an employee is a person in the service of a vendor laboratory and subject to the applicable terms, conditions, and rules of employment of the vendor laboratory.

Enhanced Detection Methods

Are those employed during or subsequent to the PCR amplification step that increases the sensitivity of the Standard Method and are typically employed with low-quantity and/or low-quality samples. These Enhanced Detection Methods include, but are not limited to, increased amplification cycle number, increased injection time and/or voltage, reduced reaction volume, nested PCR, increasing the amount of *Taq* Polymerase, and post-amplification desalting or concentration. When using Enhanced Detection Methods, the potential for stochastic effects (i.e., elevated stutter, allele drop-out, and intra-locus peak imbalance) may increase. Stochastic effects can be addressed through appropriate interpretation guidelines and relevant thresholds (e.g., an increased injection time may require the adjustment of the stochastic threshold determined from the Standard Method). Therefore, prior to any enhanced detection protocol being implemented, which may include one or more Enhanced Detection Methods, appropriate validations must be performed to address the potential increase in stochastic effects. Appropriate validations shall include assessments of stutter percentages, peak-height ratios, analytical thresholds, stochastic thresholds, locus-to-locus balances, and non-reproducible alleles.

Expungement

The deletion of a DNA profile at the State and/or national index levels in response to the following: (1) for convicted offenders, a court order that has overturned a convicted offender's conviction for a qualifying offense; (2) for arrestees, a court order documenting that the qualifying arrest charge(s) were dismissed or resulted in acquittal, or no charges were filed within the applicable time period; (3) for arrestees, a requirement for removal by the laboratory when the qualifying arrest charge(s) are dismissed, resulted in acquittal, or no charges were filed within the applicable time period.

Federal DNA Act or Federal DNA Identification Act of 1994

The enabling legislation for the National DNA Index System found at 34 U.S.C. §12592 that authorizes the FBI Director to establish a national DNA identification index for

enumerated categories of records subject to privacy and quality control requirements.

Forensic Index

A Forensic Index consists of DNA records originating from and associated with an evidence sample from a single source (or a fully deduced profile originating from a mixture) that is found at a crime scene. The Forensic Index contains Forensic Unknowns.

Forensic Mixture (Specimen Category)

A specimen category in the CODIS software that is stored in the Forensic Mixture Index and originates from a forensic sample (biological sample found at the scene of a crime) that contains DNA contributed from more than one source attributable to a putative perpetrator(s).

Forensic Mixture Index

A Forensic Mixture Index consists of DNA records from forensic samples that contain DNA contributed from more than one source. The Forensic Mixture Index contains Forensic Mixture DNA records.

Forensic Partial (Specimen Category)

A specimen category in the CODIS software that is stored in the Forensic Partial Index and originates from a single source (or a fully deduced profile originating from a mixture) Forensic Sample attributable to the putative perpetrator with either locus or allelic dropout at any of the 13 Original CODIS Core Loci. Effective January 1, 2017, an analysis of all CODIS Core Loci shall be attempted for Forensic Partial Samples.

Forensic Partial Index

A Forensic Partial Index consists of DNA records from forensic samples that do not contain results for all 13 Original CODIS Core Loci and/or that may indicate a possibility of allelic dropout.

Forensic Sample

A biological sample originating from and/or associated with a crime scene and whose source is attributable to a putative perpetrator. These are not reference samples from known individuals, such as from victims, suspects, offenders, etc.

Forensic Targeted (Specimen Category)

A specimen category in the CODIS software that is stored in the Forensic Targeted Index and originates from a forensic partial or a forensic mixture that does not meet the NDIS moderate match estimate threshold of 1 in 10 million, but does meet the match rarity estimate threshold of 1 in 10 million if searched at a specified stringency by locus (high or moderate).

Forensic Targeted Index

A Forensic Targeted Index consists of DNA records from forensic partial or forensic

mixture samples that meet the match rarity estimate of 1 in 10 million if searched at a specified stringency by locus (high or moderate).

Forensic Unknown (Specimen Category)

A specimen category in the CODIS software that is stored in the Forensic Index and originates from a single source (or a fully deduced profile originating from a mixture) Forensic Sample attributable to the putative perpetrator and contains results for all 13 Original CODIS Core Loci.

Hit

A confirmed match that aids an investigation and one or more of the case(s) involved in the match are unsolved.

Hotfix/Patch

A software correction for an error or flaw to an operational system or operational software.

Investigation Aided

A metric that tracks the number of criminal investigations where CODIS has added value to the investigative process.

Juvenile (Specimen Category)

The known sample from a juvenile (as that term is defined by the relevant jurisdiction) who is required by State law to provide a DNA sample for analysis and entry into a State DNA database. The DNA record for this specimen category may be stored in the Convicted Offender Index.

Known Sample

Biological material from an individual whose identity is established.

Laboratory

A facility: (1) employing at least two full-time employees who are qualified DNA analysts and (2) having and maintaining the capability to perform the DNA analysis of forensic and/or casework reference samples, or on database and/or known samples, at that facility.

Laboratory Support Personnel

(or equivalent role, position, or title as designated by the laboratory)

Employees or contract employees, who perform laboratory support duties exclusive of analytical procedures on database, forensic, known or casework reference samples.

Legal (Specimen Category)

The known reference sample from a person whose DNA sample is collected under applicable legal authorities (State law), provided that DNA samples that are voluntarily submitted solely for elimination purposes shall not qualify as a Legal specimen. The DNA record for this specimen category is stored in the Legal Index.

Legal Index

A Legal Index consists of DNA records of persons whose DNA samples are collected under applicable legal authorities (State law).

Live Scan

Is the electronic capture of fingerprint images; may be used to describe the device or the technology.

Low Template or Low Copy DNA Analysis

Is a subset of Enhanced Detection Methods that, in addition to the increased potential for stochastic effects, have an increased potential for non-reproducible alleles.

Manual Keyboard Search

A manual search of NDIS initiated by the NDIS Custodian.

Match

A match occurs when CODIS links two or more DNA profiles and a confirmation process is started by designated laboratory personnel from each affected laboratory.

Match Report

After CODIS determines that two or more DNA profiles potentially match, an electronic report is generated by CODIS and automatically distributed to the laboratories responsible for the matching profiles.

Maternal Relative (Specimen Category)

The known reference sample voluntarily provided by a maternal biological relative who is not a mother, child or sibling of a reported missing person. The DNA record for this specimen category is stored in the Relatives of Missing Person Index and the Pedigree Tree Index.

Missing Person (Specimen Category)

The known reference sample from an individual that is missing. The source of the DNA has been verified as originating from the missing person and is stored in the Missing Person Index.

Missing Person Index

A Missing Person Index consists of DNA records from missing persons and deduced missing persons.

Mobile Laboratory

A self-contained facility, under the administration of a single stationary parent laboratory responsible for uploading the DNA records to NDIS, that is capable of being moved to different physical locations that (1) employs at least two full-time employees onsite who

are qualified DNA analysts; and (2) maintains the capability to perform the DNA analysis of forensic and/or casework reference samples, or on database and/or known samples, at that facility.

Modified Rapid DNA Analysis

The semi-automated (hands-free) process of developing a CODIS acceptable STR profile from a database, known or casework reference sample. The "swab in – profile out" process consists of automated extraction, amplification, separation, and detection without human intervention but requires an analyst to perform manual interpretation and technical review.

Multi-allelic Offender (Specimen Category)

An offender (arrestee, convicted offender, detainee or Legal Index specimen) DNA record having three or more alleles at two or more loci.

Multi-allelic Offender Index

A Multi-allelic Offender Index consists of DNA records from offenders (arrestees, convicted offenders, detainees or Legal Index specimens) having three or more alleles at two or more loci.

Multi-laboratory state or local system

Two or more laboratories, including regional or satellite laboratories, that operate at the state or local level. A laboratory in a multi-laboratory state or local system may either upload its DNA records to CODIS in accordance with these procedures and the QAS or generate DNA records for upload to NDIS through its parent laboratory.

NDIS Audit Review Panel

A panel composed of Federal, Military, State and Local representatives from NDIS participating laboratories who are or have been qualified DNA examiners and have successfully completed the FBI's DNA auditor training program.

NDIS Privacy Act Notice

The notice on the National DNA Index System required by the Federal Privacy Act; published in the Federal Register on July 19, 1996 at Vol. 61, No. 139.

NDIS Procedures Board

A board, which may be composed of Federal, Military, State and Local representatives from NDIS participating laboratories, that has the responsibility of establishing, reviewing, and modifying NDIS operational procedures.

Next Generation Sequencing (NGS) (also known as massively parallel sequencing, deep sequencing and high throughput sequencing)

A term used to describe modern sequencing technologies other than Sanger sequencing.

Offender

This term is intended to include arrestees, convicted offenders, detainees, multi-allelic offenders and Legal Index specimens.

Offender Laboratory

The laboratory responsible to NDIS for a DNA profile developed from a reference sample provided by a known offender (e.g., Arrestee, Convicted Offender, Detainee or Legal).

Original CODIS Core Loci

The following 13 CODIS Core Loci were required for inclusion in the National DNA Index from October 13, 1998 until December 31, 2016: CSF1PO, FGA, TH01, TPOX, vWA, D3S1358, D5S818, D7S820, D8S1179, D13S317, D16S539, D18S51 and D21S11.

Outsourcing

Utilization of a vendor laboratory to provide DNA services in which the NDIS participating laboratory takes or retains ownership of the DNA data for entry into CODIS. Outsourcing does not require the existence of a contractual agreement or the exchange of funds.

Ownership review

A review of DNA records generated by a vendor laboratory in accordance with QAS Standard 17 by the NDIS participating laboratory that accepts responsibility for and will enter the DNA records into CODIS.

Paternal Relative (Specimen Category)

The known reference sample voluntarily provided by a paternal biological relative who is not a father, child or sibling of a reported missing person. The DNA record for this specimen category is stored in the Relatives of Missing Person Index and the Pedigree Tree Index.

Pedigree Tree

A Pedigree Tree contains genetic information from two or more biological relatives of missing persons (may include spouses, where applicable). A Single Typed Node Pedigree contains the genetic information from only one biological relative of the missing person.

Pedigree Tree Index

A Pedigree Tree Index consists of DNA records of biological relatives and spouses of missing persons that are associated with a Pedigree Tree.

Platform

The type of analytical system utilized to generate DNA profiles, such as capillary electrophoresis, real-time gel, and end-point gel instruments or systems.

Probabilistic Genotyping System

Is a tool to assist the DNA analyst comprised of software, or software and hardware, with analytical and statistical functions that use biological modeling, statistical theory, computer algorithms, and/or probability distributions to calculate likelihood ratios and/or infer genotypes for the DNA typing results of forensic samples.

Qualified Auditor

A current or previously qualified DNA analyst who has successfully completed the FBI's DNA auditor training course, and for purposes of eligibility for an NDIS Audit Review Panel, the individual shall have participated in, as a member of an auditing team, at least one external Quality Assurance Standards audit.

Qualified DNA Analyst

A DNA analyst who has satisfied and continues to satisfy the experience, education, training, proficiency testing and continuing education requirements of the FBI Director's Quality Assurance Standards (Standards 5 and 13), issued in accordance with the DNA Identification Act of 1994, as well as successful completion of a qualifying test prior to beginning casework or databasing responsibilities.

Quality Assurance Standards (QAS)

Minimum standards for a quality assurance program for forensic DNA analysis issued by the Director of the Federal Bureau of Investigation in accordance with 34 U.S.C. §12591.

Rapid DNA Analysis

The fully automated (hands-free) process of developing a CODIS acceptable STR profile from a database, known or casework reference sample. The "swab in – profile out" process consists of automated extraction, amplification, separation, detection and allele calling without human intervention.

Rapid DNA Booking System

A fully automated system, used in a booking agency, to produce a CODIS acceptable DNA profile from an arrestee buccal swab without human interpretation in under two hours.

Rapid DNA Cartridge

A preassembled set of reagents and other analytical components (such as typing test kit) designed for use in a Rapid DNA instrument/System for the extraction, amplification and/or separation of DNA samples.

Rapid DNA Instrument

Instrumentation that carries out a fully automated process to derive a DNA analysis (CODIS compatible STR profile) from a database, known or casework reference DNA buccal sample.

Rapid DNA System

The collection of components that together performs Rapid DNA analysis consisting of a Rapid DNA instrument, the PCR STR typing kit/Rapid DNA cartridge, and an integrated Expert System used to develop a CODIS acceptable STR profile from a database, known or casework reference buccal sample.

Relatives of Missing Person Index

A Relatives of Missing Person Index consists of DNA records from the biological relatives of individuals reported missing.

Solved Case

A case or criminal investigation for which a putative perpetrator has been identified and/or charged with a criminal offense.

Spouse (Specimen Category)

The known reference sample voluntarily provided by a presumptive parent of a common child. The DNA record for this specimen category is stored in the Spouse Index and the Pedigree Tree Index.

Spouse Index

A Spouse Index consists of the DNA records of a presumptive parent of a common child of a missing person.

Standard Method

Is the method routinely employed to generate a complete profile for single-source samples of high quality and quantity. The Standard Method can be applied to all sample types – including mixtures, low-quantity samples, and low-quality samples – wherein data obtained meet the criteria defined through internal validation as reliable. This method is typically not sensitive enough to detect drop-in.

Target DNA Profile

A DNA profile submitted by an NDIS participating laboratory for the purpose of searching DNA profiles maintained by NDIS which could match an indexed DNA profile.

Technician

(or equivalent role, position, or title as designated by the laboratory)

An employee or contract employee who performs analytical procedures on database, forensic, known or casework reference samples under the direction of a qualified analyst. Technicians do not interpret data to reach conclusions on typing results or prepare final documents/reports.

Technology

A term used to describe the type of forensic DNA analysis performed in the laboratory, such as RFLP, STR, YSTR, or mitochondrial DNA.

Test Kit

A preassembled set of reagents that allows the user to conduct a specific DNA extraction, quantitation, or amplification.

Unidentified Human (Remains) Index

An Unidentified Human (Remains) Index consists of DNA records from recovered living persons (e.g., children who cannot and others who cannot or refuse to identify themselves), and recovered dead persons (including their body parts and tissues) whose identities are not known.

Unidentified Person (Specimen Category)

The DNA profile developed from the recovered deceased (including body parts and tissue) or an individual who is unidentified (e.g., children who cannot and others who cannot or refuse to identify themselves). The DNA record for this specimen category is stored in the Unidentified Human (Remains) Index.

Unsolved Case

A case or criminal investigation for which no suspect has been identified and/or charged with a criminal offense. An unsolved case is equivalent to 'No suspect case' and 'Unsub case'.

Vendor Laboratory

A governmental or private laboratory that provides DNA analysis services to another laboratory or agency and does not take ownership of the DNA data for purposes of entry into CODIS.